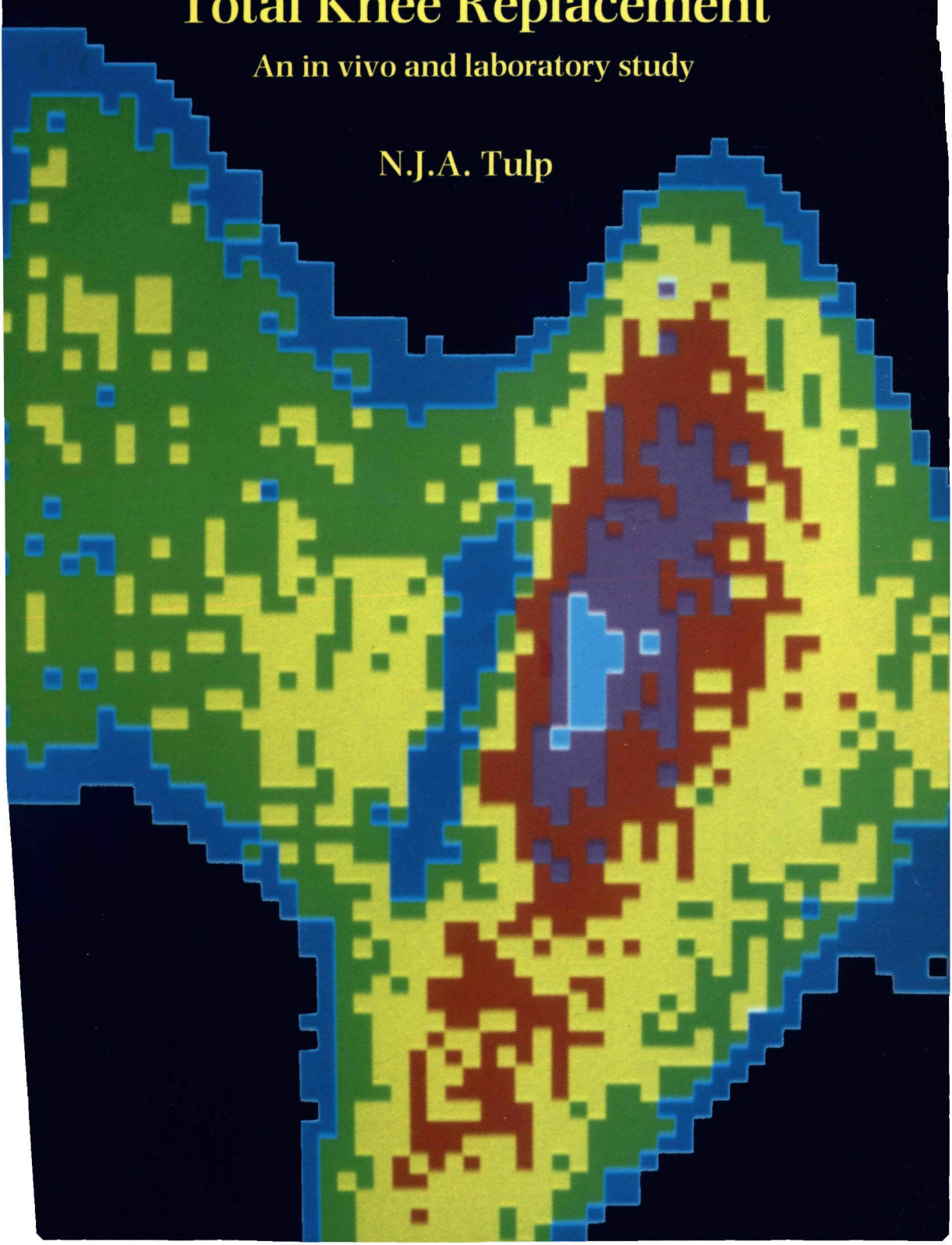
Wear and Alignment in Total Knee Replacement

An in vivo and laboratory study

N.J.A. Tulp



WEAR AND ALIGNMENT IN TOTAL KNEE REPLACEMENT

AN IN VIVO AND LABORATORY STUDY

Een wetenschappelijke proeve op het gebied van de
Medische Wetenschappen

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aan de Katholieke Universiteit Nijmegen, volgens besluit
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VOORWOORD

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CONTENTS

1. INTRODUCTION

1.1 Problem definition and outline of the study.

Several kinds of surgical treatment are now available for the destroyed knee joint. In the past, an arthrodesis was the treatment of choice for the severe cases. Later, the correction osteotomy was developed for patients with a varus or valgus deformity, suitable if the contralateral compartment is not severely damaged (Maquet, 1980; Coventry, 1988). Another possibility in these patients is the implantation of a uni-condylar knee prosthesis, especially in the older ones (Marmor, 1979, 1984; Bernasek et al., 1988) although material failure, especially of the tibial component, has proven to be a problem (Marmor, 1988; Christensen et al., 1990; Hoshino and Wallace, 1987). For patients with severe arthritic destruction in both compartments, the implantation of a Total Knee Replacement (TKR) has become a possibility.

Total Knee Replacement has seen a development in the last 30 years from single hinge-type designs, constrained in all movement directions but flexion-extension, to sophisticated, unconstrained artificial components which closely mimic the natural condyles of proximal tibia and distal femur. The eventual design objective, of course, has been on the one hand to allow for the complex, normal knee-motion characteristics, while maintaining adequate passive stability, and on the other hand to guarantee long-term mechanical integrity of the components and their fixation to bone.

These two requirements, normal motion characteristics and long-term mechanical integrity, present a principle design conflict for the TKR components. The first requirement implies that the components must be able to axially rotate relative to each other, in addition to the flexion-extension rotation. They must also be able to shift in the anterior-posterior and medial-lateral directions. In Total Condylar types of designs, this can only be realized by restricting the contact-surface constraints, hence by limiting the contact areas. This automatically implies high contact stresses and the risk for long-term failure and wear of the polyethylene tibial component, which is the principal focus of this study.

Wear of the tibial component is, of course, not the only problem. Many clinical complications are from patellar origin, and include loosening, fractures and (sub)luxation. Tibial component subsidence and loosening are also frequent complications. Femoral component problems are rare. However, by-and-large, TKR has become a succesful treatment for the severely disabled knee. Survival analyses of Total Condylar types have shown that similar survival rates as for Total Hip Replacements are feasible (Dobbs, 1980; Ranawat and Boachic-Adjei, 1988).

Success or failure of TKR depends on patient, prosthetic and surgical factors. Patient factors, such as body weight, activity level, ligament and bone quality, systemic ailments, can be influenced by indication and instruction, both the responsibility of the surgeon. Manufacturing prosthesis is the responsibility of companies. Designs are usually developed in collaboration with biomechanical research centers and orthopaedic clinics. As designing knee prostheses in particular requires the art of compromise, each inventor

and each company attempts to solve the design conflicts in their own way, and new solutions or improvements of old solutions emerge frequently. These developments are often driven by new inventions, improved materials, clinical information and biomechanical research data However, artificial joint prostheses is also big business and orthopaedic companies are forced to bring new prosthetic types on the market frequently in order to maintain their market share Hence, commerce is another incentive for development

The question then arises whether all these new types and features put to the market are really improvements where it concerns their performance and long-term endurance. Are they safe? Are they properly pre-clinically and clinically tested? These questions are the more important for the Dutch Orthopaedic surgeon when he realizes that there is no government regulation whatsoever in The Netherlands which guarantees the safety of implants (Faro, 1990), that pre-clinical or clinical testing data is often unavailable, that he does not have enough knowledge about biomaterials and biomechanics to judge the design himself, and that if indeed a prosthesis is unsafe, it may take years and many victimized patients to find out. There are many examples of such unfortunate developments of this kind in Orthopaedics, such as the Wagner surface replacement (Strens, 1985) and the use of carbon-reinforced polyethylene for knee-joint bearing material (Wright et al , 1988)

The surgical factor is the predominant responsibility of the surgeon He must insure proper implantation and fixation Knee replacement is a complicated procedure and one of the most important aspects is alignment of the artificial components relative to the bones (Bagren et al , 1983, Laskin 1984, Jonsson et al , 1988) Malalignment has effects on function, particularly of the patella, on endurance, in relation to tibial-component loosening, and probably also on wear. In order to obtain proper alignment and fixation, surgical instruments are used which are the inherent parts of a particular design. Although the surgeon is responsible for the surgical procedure, the companies provide the instruments and the instructions for their use And again the question arises whether these instruments really accomplish what they are intended for Are they properly tested? Are the instructions clear and adequate for the orthopaedic surgeon at large? But also, is the general orthopaedic surgeon adequately trained to use them properly? How much experience does one require to maintain acceptable succes rates?

Wear in Total Knee Replacement is the central topic of this study. The questions raised above form the background for its treatment Of course, the questions are all generic ones, and can not truly be answered definitely here But an attempt is made to shed some light on the relevance of the questions in what can be considered a 'case study' The 'case' in question is the PCA (Porous Coated Anatomic) Total Knee Replacement, which is used as a model of modern Total Condylar TKR in several clinical and laboratory investigations. Its design and surgical instruments are discussed in the remainder of this chapter In Chapter 2 the question is addressed how well an arbitrary group of (Dutch) peripheral orthopaedic surgeons can handle this prosthesis Or, in other words, how do their general clinical results compare to those of other series.

In Chapter 3, TKR wear in general is discussed and, using retrieval analysis, excessive

PCA wear is related to prosthetic factors The question of implant safety and preclinical testing is addressed here In Chapter 4 it is proven that there is a clear relation between wear rates and malalignment, based on a laboratory study In Chapter 5 the question of the surgical instruments is discussed, relative to malalignments Using radiological evaluation-methods on the patient series introduced in Chapter 2, the frequency and extent of malalignment is established It is also studied why malalignment occurs, a matter relating to instruction, training and experience, as discussed above.
Finally, in Chapter 6, the findings are discussed in relation to the generic questions posed in this introduction It is concluded that these questions are very relevant indeed, and should become subject of a wider interest urgently.

1.2 History of knee arthroplasty

The first report of a successful knee arthroplasty was from Ferguson (1861) It was in fact a resection of the joint, and the patient remained satisfied during five years follow-up In 1890 Gluck described a system employing ivory units for total joint replacement, on which the modern knee arthroplasty is based. The fixation of the units to the bone was a problem, a mixture of pumice and plaster was tried (Riley, 1976) In the twentieth century, different materials were used for interposition between the worn surfaces of the joint This was not a new idea, but had already been described in 1860 (Verneuil, 1860) At first only autologous tissue was used. Murphy (1913) and Albee (1928) used fat and fascia lata, and Putti tried using fascia lata only (1921). The prepatellar bursa was used by Campbell (1921), and Brown (1958) reported the use of skin as an interposition Foreign materials were also used, such as chromosized pig bladder (Baer, 1918), cellophane (Sampson, 1949) and sheets of nylon (Kuhns and Porter, 1950)
Influenced by the development of the metallic molded hip arthroplasty (Smith-Peterson, 1939), Boyd developed vitallium plates which fitted over the affected distal femur (Campbell, 1940) This, however, was only made possible by the work of Venable and Stuck (1938), who showed that vitallium, a chromium/cobalt/molybdenum alloy was a very biocompatible material A molded distal femoral type prosthesis was designed and used at the Massachusetts General Hospital (Jones et al., 1967). Others developed a metal tibial component (McKeever, 1960, MacIntosh, 1966). Even in a later stage these metal components were used (Swanson et al , 1985). But with all these types of prostheses used between 1914 to 1953, only a 46% success rate was achieved (Walldius, 1957). The first hinged prostheses were made of acrylate (Judet et al., 1947, Walldius, 1953). But soon the Walldius prosthesis was changed to a metal one. Modifications to this prosthesis were made by Seddon in 1952, Jackson Boroughs in 1954 (Apley, 1972), and in a later stage by Shires (1965) In England, Shiers (1954) developed and implanted his own full metal hinged prosthesis.
The next real progress was again based on new developments in hip replacement surgery The use of high density polyethylene as a prosthetic component and methylmetacrylate for fixation (McKee, 1966, Charnley, 1972) were the ingredients for the first non-hinged

prosthesis, designed by Frank Gunston during his visit at the Wrightington clinic of Charnley The first polycentric knee arthroplasty was implanted in 1968 (Gunston, 1971) This prosthesis, consisting of two semicircular steel runners. cemented in the femoral condyles, and two grooved tracks of polyethylene, cemented in the medial and lateral tibial plateaus, yielded good results, as reported by several authors (Bryan, 1971, Cracchiolo, 1973, Gunston 1973) In a later stage, however, the complications (infection in 7% and loosening in 10% of the cases) were also reported (Gunston, 1976)

From this time on, independent developments of the hinged and non-hinged prostheses occurred. Two successfull hinged prostheses were the Guepar and the Stanmore (Witvoet, 1973, Lettin et al., 1978), which did not allow any axial rotation New models were designed which did allow for some rotation and a less rigid fixation of the two components Examples are the Sheehan prosthesis in 1971, the Attenborough in 1973, the GSB-prosthesis, and the Spherocentric knee in 1973 (Matthews et al , 1973; Attenborough, 1978, Sheehan, 1978, Gschwend, 1988)

There also was a rapid development of the non-hinged protheses, but the basic elements of Gunston's ideas remained intact. the use of resurfacing components and reliance on the knee ligaments for stability In 1971 the Duocondylar and the Geometric prostheses were used for the first time (Coventry et al , 1972, 1973, Ranawat et al , 1973, 1976) The four components of the Polycentric prosthesis were reduced to one for the femur and one for the tibia Because the prostheses had to mimic the kinematics of the knee, and because of cruciate ligament retention, high constraint forces often led to loosening Freeman and Swanson in 1969/70 designed a two-component prosthesis requiring resection of the cruciate ligaments (Freeman and Swanson, 1972) It was again Freeman who was responsible for the development of a set of special instruments to control the position of the components and for the principle of tensioning the joint prior to implantation (Freeman et al., 1973)

With the introduction of the 'Total Condylar' knee replacement in 1973, a new period in the history of total knee replacement surgery began Based on the biomechanical work of Walker, the curvature of the components followed more closely the anatomical shape of the human condyles A patella resurfacing prosthesis could also be used (Walker, 1973, Insall et al , 1976,1979)

In 1975, the first uncemented resurfacing total knee arthroplasty was performed (Ring, 1980) Soon afterwards, many other kinds of uncemented prostheses followed (Blaha, 1982, Hungerford, 1983) and at the present time most knee prostheses can be used either with or without cement In most cases, a porous coating is employed for bone-ingrowth fixation.

In the knee prostheses presently used, the constraints have been reduced, hence the freedom of motion increased, because the forces associated with the constraints are believed to be responsible for component loosening This reduction of constraints has also resulted in smaller contact areas between tibia and femur As a direct consequence of this smaller contact area, the contact stress increased, which led to a higher risk of polyethylene wear A few designers tried to solve this problem by creating a meniscal bearing prosthesis (Goodfellow and O'Conner, 1978, 1986, Buechel and Pappas, 1986) The re-

duced constraints also increased the laxity of the knee. To guarantee adequate stability, practically all these prostheses are posterior-cruciate retaining and in some of them both cruciate ligaments can be spared.

1.3 Characteristics of the PCA

The PCA (Porous Coated Anatomic) total knee prosthesis has been developed over a period of years, and this has resulted in three subsequent types. The first one was in production until 1982. The PCA 'modular' prosthesis (Hungerford, 1988) is in production since 1988. From 1982 up to 1988 the PCA 'primary prosthesis' was produced by Howmedica. This one was used in the present clinical series, and will be briefly introduced here.

The primary PCA is one of the modern prostheses with low constraints, small contact areas and posterior-cruciate retainment (Fig. 1.1). It was developed on an anatomical basis (Kenna et al., 1984). This resulted in an asymmetric design of the femoral component, with different medial condylar, lateral condylar and intercondylar radii. In the coronal plane the surface-contours of the condyles were flat. There were left and right configurations and the femoral component was available in four sizes.

The tibial design was also asymmetric and made in left and right configurations. The surface showed a flat area in the center of the plateaus. There was a more concave shape at the front as well as at the back of the medial side. This resulted in a relatively stable

Figure 1.1:
The Porous Coated Anatomic (PCA) primary total knee replacement

medial compartment with some freedom of motion on the lateral side in flexion In this way a nearly normal freedom of rotation was available There were 20 tibial components available, 4 sizes each in 5 thicknesses. All tibial components consisted of a metal tray of about 3 mm thickness and on this a polyethylene layer of 4 to 13 mm thick For fixation two options were available One component was medially and laterally pegged (Fig. 1 1), with the possibility of an additional screw, to be used with or without cement The other option was a centrally stemmed model for implantation with cement only.
The patella prosthesis was available in three sizes and had a larger lateral than medial facet, as in the natural patella The patella femoral groove of the femoral component ran 3 degrees laterally and the anterolateral flange of this groove was prominent. This should provide good patella-femoral joint stability and tracking (Kenna et al 1984). Two pegs in the metal backing had to be used for fixation of the patella, either with or without cement.
The prosthesis was made out of Vitallium A porous coating of cobalt-chrome beads was sintered to the inner surface. A double layer of beads formed a three-dimensional porous surface with an average pore size of 425 microns. With this porous coating, cementless use of the components was possible Although an optimal pore size was thought to be between 50 and 400 microns (Bobyn et al., 1980, Pilliar, 1983), a slightly larger size was chosen because of the micromovements of the components at the interface In April 1988 the sintering technique was changed in order to achieve better bonds between the beads (Howmedica, 1988)
The flat surface of the tibia and the cylinder shaped femur resulted in a line type contact area, with low constraints in torsional and shear forces The prosthesis relied partially on the collateral ligaments and the posterior cruciate ligament of the knee for stability In order to reduce friction in the contact surfaces, the polyethylene was given a surface heat treatment which created a smooth shining surface.

1.4 Alignment

The alignment of the leg in the frontal plane has important effects on the function of the knee (Rozing, 1976). It is defined by anatomical and biomechanical parameters Relative to the femur (Fig 1.2 a.) we define the femoral shaft axis, which runs through the center of the knee and the central diaphysis, and the transverse femoral axis, which is the tangent to the frontal contours of the condyles, these are both anatomical axes The lateral angle between these axis is denoted by $\alpha 1$. Further we define the mechanical femoral axis, which runs through the center of femoral head and the center of the knee The angle between the femoral mechanical axis and the femoral shaft axis is denoted by $\alpha 2$ The lateral angle between the femoral mechanical axis and the transverse femoral axis is denoted by $\alpha 3$ It is obvious that $\alpha 1 + \alpha 2 = \alpha 3$.
Relative to the tibia (Fig. 1 2 b.) we define the mechanical tibial axis, which runs from center knee to center ankle, and the transverse tibial axis, which is the tangent to the frontal contours of the tibial plateaus

The medial angle between these axes is denoted by β.
Relative to the whole leg (Fig. 1.2.c.) we define the mechanical axis of the leg, which runs from the center of the femoral head to the center of the ankle, and the transverse knee axis, which connects the centers of the contact areas of the knee in the lateral and medial compartments. The angle between the femoral shaft axis and the mechanical tibial axis is denoted by γ1. The medial angle between the transverse knee axis and the mechanical axis of the leg is denoted by γ2.
In the normal leg, the mechanical axis of the leg runs through the center of the knee joint, hence the mechanical axes of the femur, the tibia and the whole leg coincide. That also implies, that, in the *normal* case, α2 = γ1, and that β = γ2.
But it must be remembered that the α-angles are related to femoral anatomy only, the β-angles to tibial anatomy only, and the γ-angles to the whole leg (Fig. 1.2.d).
It is easily recognized that, given the particular anatomical dimensions of a femur and a tibia, their combination will be aligned properly only in the case that α3 = β. The reason for this is, that in combination, the transverse femoral and tibial axes merge to coincide with the transverse knee axis. In knee replacement, angle α3 coincides with the lateral angle between the femoral component and mechanical femoral axis, and the angle β with the medial angle between the tibial plateau and the mechanical tibial axis. Hence, the

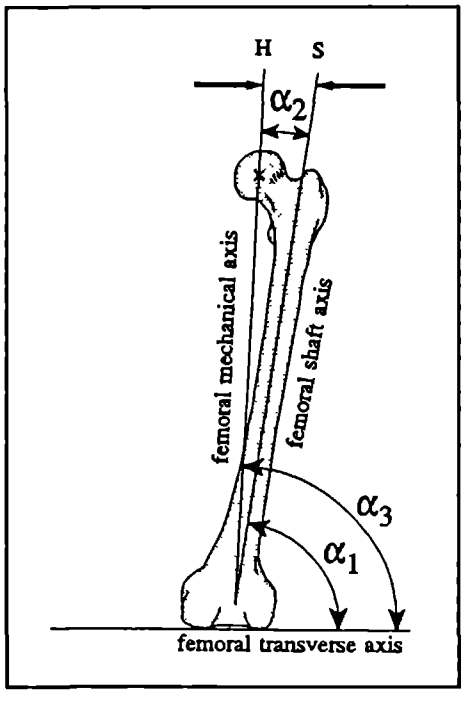


Figure 1.2a:
Anatomical and biomechanical parameters of the femur

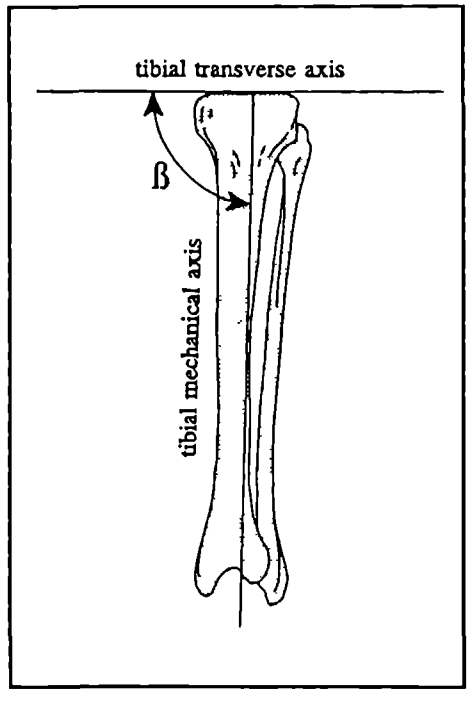
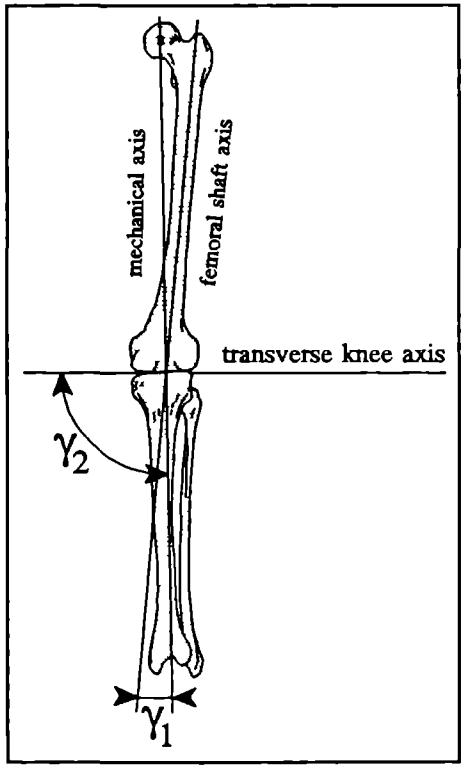


Figure 1.2b:
Anatomical and biomechanical parameters of the tibia

first goal of prosthetic component alignment is to guarantee that $\alpha 3 = \beta$. When this is accomplished, the mechanical axis of the leg will run through the center of the knee. The second goal of prosthetic alignment is to provide the correct value for $\gamma 2$, the angle between the transverse knee axis and the mechanical axis of the leg. What this correct value is, is a matter of debate (Kenna et al., 1984), but according to the concept of the PCA it should be 87 degrees in order to achieve a horizontal transverse axis of the knee in stance and gait. Since $\gamma 2 = \alpha 3 = \beta$ if the knee is properly aligned, this means that the prosthetic alignment goal becomes $\alpha 3 = \beta =$ 87 degrees.

In order to reach this goal, alignment instruments are used for femur and tibia, which are particular to the type of prothesis used. The correct value for $\gamma 2$ is still a matter of debate, and different designers propose different angles. As said, the PCA designers assume it must be 87 degrees. There are also other differences in the instruments used for different prostheses, e.g. relative to the anatomical reference philosophy or the priority of femoral versus tibial sectioning. The PCA instrument for the tibia is shown in Fig. 1.3. It provides an extra-medullary approximation of the tibial mechanical axis, based on



Fiqure 1.2c:
Anatomical and biomechanical parameters of the leg

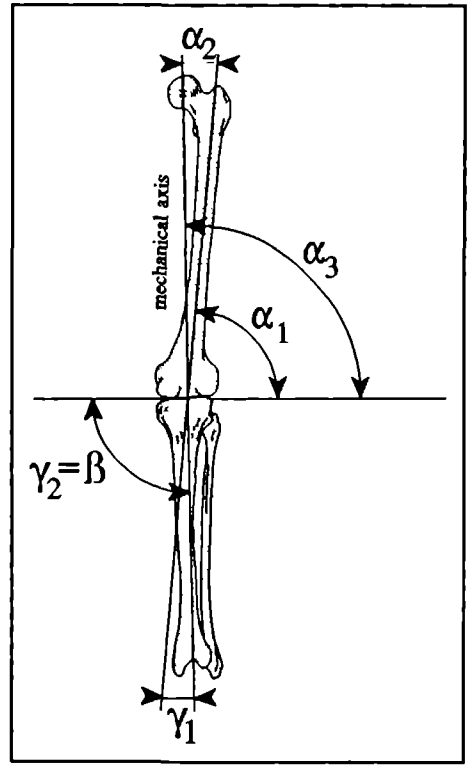


Figure 1.2d:
Anatomical and biomechanical parameters of the femur, tibia and leg combined

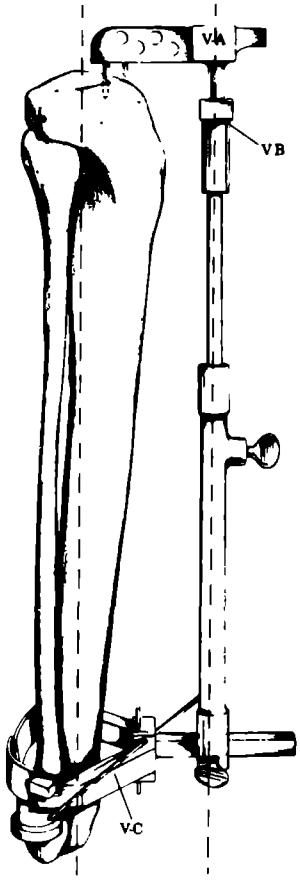


Figure 1.3:
Extra medullary aiming/cutting jig for the tibia

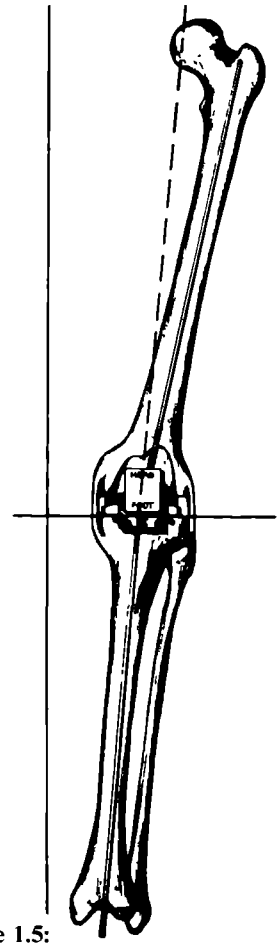


Figure 1.5:
Intra operative alignment guide

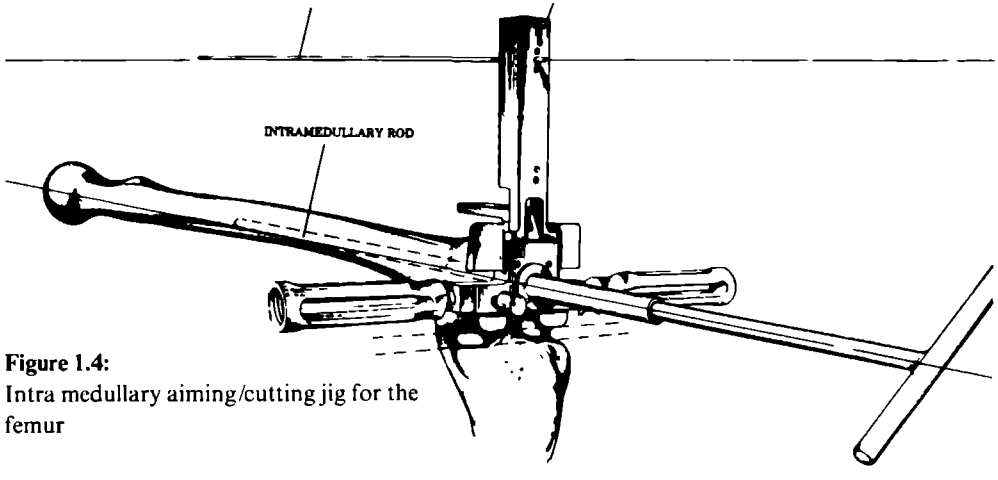


Figure 1.4:
Intra medullary aiming/cutting jig for the femur

which a bone cut under a 87 degree angle can be made. Hence it is used to create the angle β, the tibial component angle.
The femoral alignment guide is an intramedullary one (Fig. 1.4), giving a reference for a femoral bone cut. Hence, the angle $\alpha 1$ is created, between the femoral shaft axis and the transverse femoral axis (or the femoral component angle), according to Fig. 1.2.a.
This angle must equal 87-$\alpha 2$ degrees, since $\alpha 3 = \alpha 1 + \alpha 2$ must be 87 degrees.
Hence, the angle $\alpha 2$ must be established radiologically before the operation to ensure the use of the correct angle of the femoral guide.
Once the femoral cut is made, the femoral component angle $\alpha 1$ is definite and hence also the angle $\alpha 3$ is established (Fig. 1.2.a). If the femoral component angle is erroneous, perfect alignment can still be accomplished if the same error is made in the tibial component angle β. Of course, in that case the angle $\gamma 2$, between the mechanical axis of the leg and the transverse knee axis will deviate from 87 degrees. In order to check alignment during the operation and give the possibilities for corrections, the PCA instrumentation includes an intra-operative guiding instrument (Fig. 1.5).

2. CLINICAL MATERIAL

2.1 Characteristics of the patient series

Seven Dutch clinics were visited and patients with a PCA knee prosthesis studied. The reasons for this multi-center study were to see if the Dutch orthopaedic surgeon was capable of achieving good alignment and primary stability needed for biological fixation (bone ingrowth), and to evaluate their results in comparison with those reported in the literature.

In this clinical multi-center study 107 patients with 121 PCA primary total knee replacements were considered. In fourteen patients a bilateral prosthesis was implanted. Eighty-nine patients were females and 18 males. Their ages at the time of operation ranged from 35 to 87 years, with an average of 67 years. The period of follow-up was at least two years; the longest was six years and two months. The mean follow-up period was three years and two months. The number of surgeons who performed the operation was about 12.

Osteoarthritis was the diagnosis in 78 cases (64%) and rheumatoid arthritis in 36 cases (30%). The diagnosis of secondary arthritis had been made in 7 cases (6%); the previous operations are discussed below. The prosthesis was placed uncemented in 93 cases (77%) and cement was used in 28 prostheses (23%), of which in seven both components were cemented.

The author personally scored all patients according to the 100 point scale of the Hospital for Special Surgery (H.S.S. score). An excellent result implied a score of more than 85 points, a good result between 70 and 84 points, fair between 60 and 69 points, and poor results less than 60 points (Insall et al., 1976).

Radiological evaluation was also carried out. Full-leg length, weight-bearing radiograms were made to check the alignment of the prothesis. The position of the mechanical axis of the leg relative to the center of the knee joint was chosen as a parameter to evaluate alignment. In the literature, the tibio-femoral angle is commonly used. Reasons to choose the position of the mechanical axis as a parameter for the alignment are first of all because it is less influenced by limb rotation on the radiogram (Goodman et al., 1989), secondly because the center of the PCA knee can be located easily on its radiological appearence. An important disadvantage is that there are no references for the position of the mechanical axis in the literature for what can be considered as an acceptable alignment. For the tibio-femoral angle a 4 to 10 degrees valgus angle is defined as an acceptable alignment in the literature, although there still is some debate (Townley, 1985; Insall et al., 1985; Peterson and Engh, 1988; Insall et al., 1989). By measuring both the tibio-femoral angle and the position of the mechanical axis it is possible to calculate an acceptable alignment for the position of the mechanical axis by a linear regression analysis. Standard X-rays were made to check for bone-prosthesis contact, radiolucencies and loose chrome-cobalt beads. The tracking of the patella was evaluated on the skyline view.

2.2 Clinical results

The average H.S.S. scores for the entire group were 40 points pre-operatively and 80 points post-operatively. Fourty percent of the patients had an excellent score and 45% a good score. Of the patients with a pre-operative H.S.S. score of less or equal to 30 points (n = 18) only 22% were excellent postoperative. However, 83% of these were either excellent or good. When the pre-operative H.S.S. score was equal to or higher than 50 points (n = 26), 54% of the patients had excellent scores and 34% good scores. This suggests that a lower pre-operative score results in a lower post-operative score, at least in most cases.

Figure 2.1 shows the average pre- and post-operative scores for the osteoarthritis, rheumatoid arthritis and secondary arthritis groups. In Fig. 2.2 the percentages of excellent, good, fair and poor results are shown for the different patient groups. In the osteoarthritis group, the result was excellent or good in 88.5% and for the rheumatoid group in 86% of the cases. Although the differences in H.S.S. scores for the osteoarthritis and the rheumatoid arthritis groups suggest a better result for the O.A. group, this difference in score proved to be not statistically significant (Mann - Whitney test). The results were disappointing in the secondary arthritis group, with 28.6% excellent or good scores. The average post-operative score was 65.7, and the average improvement only 26 points. This proved to be statistically different from the results in the other two groups (Mann - Whitney test $p < 0.001$) . Table 2.1 presents the scores for the different diagnoses of the patients in this secondary arthritis group.

The prostheses were placed uncemented in the majority (n = 61) of the patients with osteoarthritis: only four were fully and 13 partially cemented (the tibial component), so-

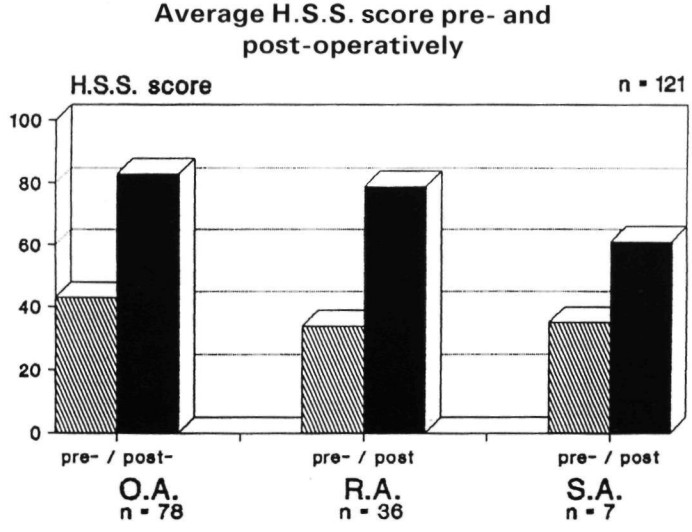


Figure 2.1:
Average H.S.S. score pre- and post-operatively

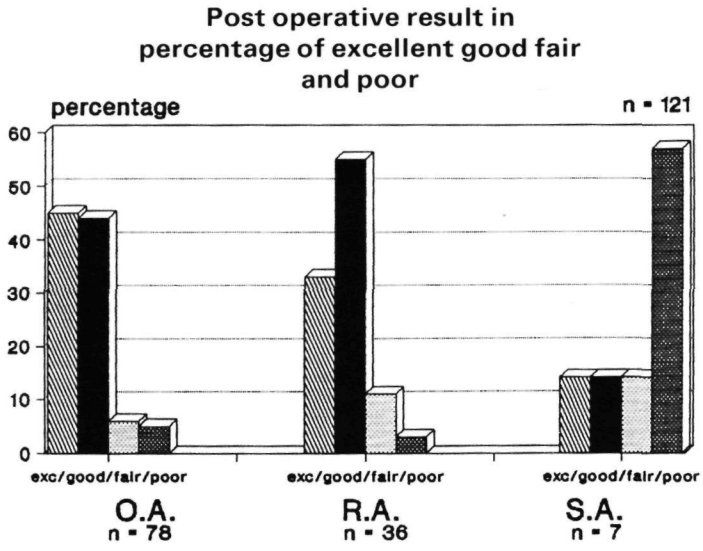


Figure 2.2:
Post-operative result in percentage of excellent, good, fair and poor

called hybrids. No differences in results (Mann-Whitney test) were found (Fig.2.3) . In the osteoarthritis group, a linear regression analysis was carried out in order to see if there was any correlation of the H.S.S. scores with age, body weight, or length of follow-up period. Only for the length of time since implantation a significant relation was found ($p < 0.05$). The analysis is shown in Fig. 2.4. The H.S.S. score is lower for increasing follow-up period.

H.S.S. score secondary arthritis patients

diagnosis	pre-operative	post-operative
post trauma n = 5	40	65
achondroplasia n = 1	25	53
post tuberculosis n = 1	22	57

Table 2.1:
H.S.S. score for the secondary arthritis patients

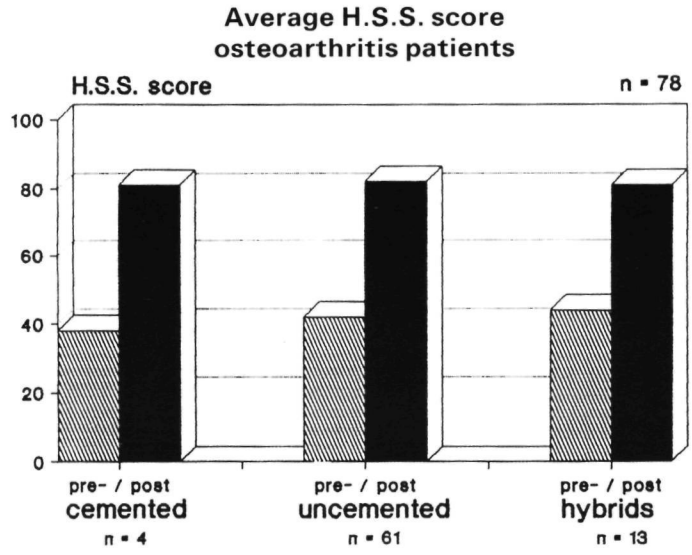


Figure 2.3:
Average H.S.S. score for the osteoarthritis patients

There was also a significant difference between patients who had undergone previous operations and those who had not. Patients with one or more previous operations (n = 27) yielded a mean score of 79 H.S.S. points, whereas the score was 83 points in those

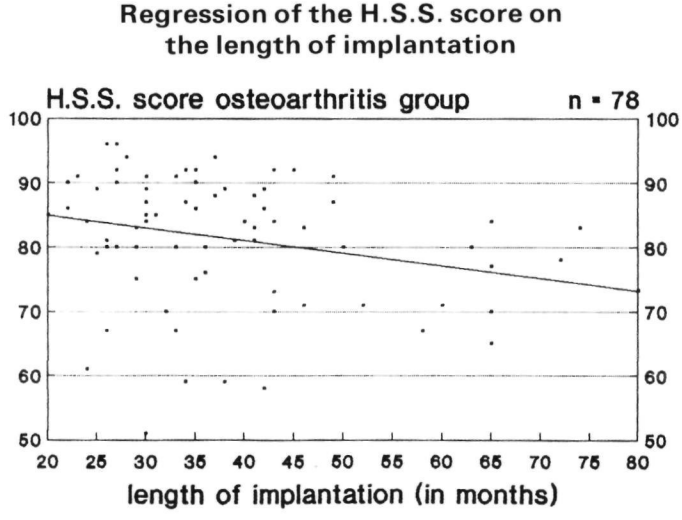


Figure 2.4:
Linear regression analysis of the H.S.S. score on the length of implantation

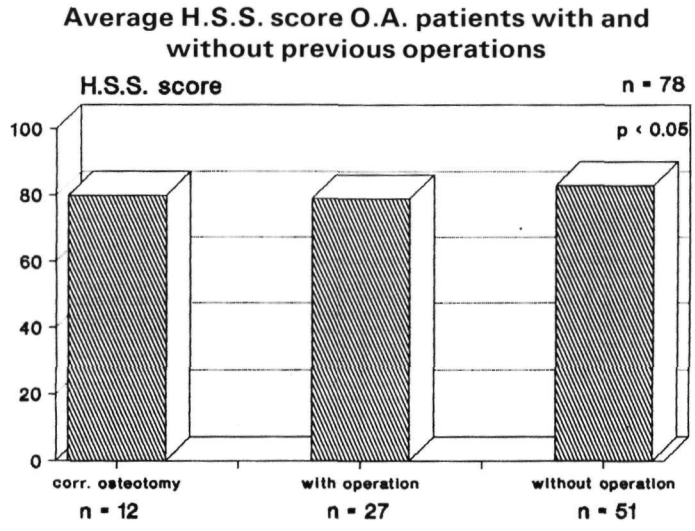


Figure 2.5:
Average H.S.S. score of the osteoarthritis patients with and without previous operations

without (n = 51; Mann - Whitney test $p < 0.05$). A correction osteotomy had been carried out in 12 patients (upper tibia or supracondylar femur), but this had no significant influence on the H.S.S. score compared to the patients without previous operations

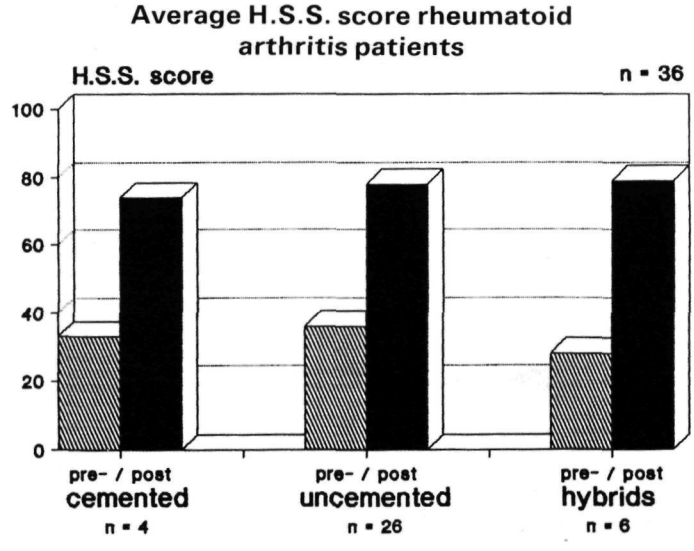


Figure 2.6:
Average H.S.S. score of the rheumatoid arthritis patients

(Fig. 2.5). Nor were other operations, such as meniscectomy or arthroscopy, of significant influence. But when two or more operations had been performed (n = 13) a significant effect was apparent (Mann-Whitney test $p < 0.001$).
No influence was found in the rheumatoid arthritis group between patients whose prostheses were cemented and those who were not, or were partially cemented, as shown in Fig. 2.6 (Mann - Whitney test). The length of follow-up, the age of the patient or the body weight yielded no significant differences in the rheumatoid arthritis group. There were 11 patients in this group who had a synovectomy of the knee before the prosthesis was implanted. Their average H.S.S. score was 77 points, which was not significantly different from the average of 80 points in the other 25 rheumatoid arthritis patients (Mann - Whitney test).
Not all the separate parts of the H.S.S. score are discussed here, but an exception is made for the function of the knees. The average maximal flexion angles were 97 degrees pre-operatively and 95 degrees post-operatively. No significant difference was found with the Wilcoxon test, but the difference in the average flexion contracture of 10 degrees pre-operatively and two degrees post-operatively was significant ($p < 0.001$) as shown in Fig. 2.7.
The stability of the knee was a factor which had a considerable influence on the function of the joint. An anteroposterior shift of more than 5 mm or a mediolateral movement of more than 5 degrees were assessed as instability. An average range of motion of 83 degrees for the stable knees ($n=47$) compared to 99 degrees for the unstable ones ($n=74$) proved to be statistically different ($p<0.001$). In the majority of cases (n = 35) a combined anteroposterior and mediolateral instability was found. In those cases where only anteroposterior instability was evident (n = 17), the significance level was the same.

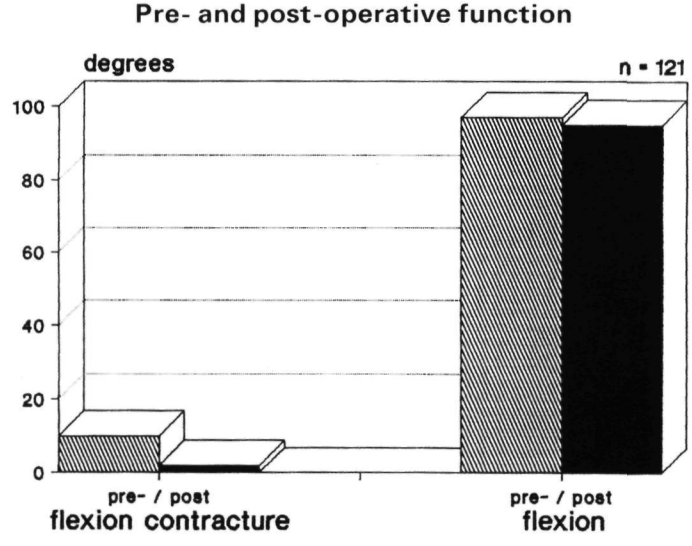


Figure 2.7:
Average pre- and post-operative knee function

The post-operative flexion range in the group with only mediolateral instability (n = 22) was still significantly better than the one in the group with stable knees (Mann - Whitney test, $p < 0.05$). This means that not only an insufficient posterior cruciate ligament yields a better flexion result of the prosthesis, but also a collateral ligament insufficiency.
Mobilization under anaesthesia, for a poor function at 3 to 4 weeks post-operative, was done only seven times and the average post-operative flexion at follow-up was 87 degrees in this group. This did not differ from the entire group, but because of a lack of data the average degree of flexion before mobilization can not be given.
Continuous passive motion (C.P.M.) was used in 94 cases. In some clinics it was used routinely and in others it was never used because it was not available. The average flexion at follow-up for the patients with C.P.M. was 95 degrees, the same as that of the entire group. In these 94 patients, manipulation under anaesthesia was performed 5 times (5.3%). In the 27 cases without C.P.M., manipulation under anaesthesia was necessary in 2 patients (7.4%)

2.3 Radiological results

The post-operative alignment achieved, shown in Fig. 2.8, clarifies that the results were certainly not perfect. With a linear regression analysis of the tibio-femoral angle on the position of the mechanical axis (Fig. 2.9), it was calculated that an acceptable alignment of 4 to 10 degrees of the tibio-femoral angle corresponds with a position of the mechani-

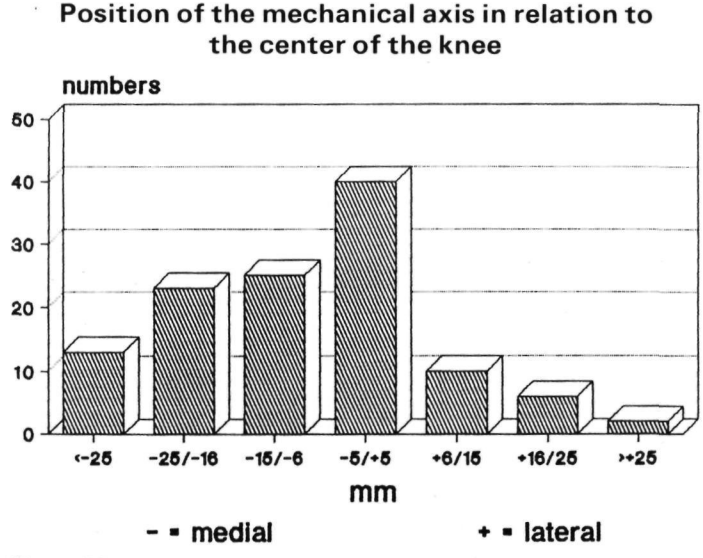


Figure 2.8:
The position of the mechanical axis in relation to the center of the knee

cal axis between 1 cm medial and 1.5 lateral to the center of the knee (R-squared 75.69% correlation coefficient 0.87, standard error of estimation 1.95). When these values are used as a criterion for acceptable alignment, the result can be considered as poor (Fig. 2.10). In 45% of the cases the position of the mechanical axis was more than 1 cm medial and in 7% more than 1.5 cm lateral to the knee center. For evaluation of the effect of alignment on the H.S.S. score, two groups of patients were analyzed, one with excellent alignment (the mechanical axis within 0.5 cm of the center of the knee) and the other with poor alignment (the mechanical axis more than 2 cm medial or lateral to the knee center). These two groups were chosen because they showed a clear difference in alignment. But the clinical results, shown in Table 2.2, revealed no significant difference (Mann - Whitney test).

Loose chrome-cobalt beads were found in 78 cases, 14 times around the patella component, 34 times around the femur and 57 times under the tibial component; in some cases the beads were seen around two or all three components. Two-hundred-twenty loose beads were counted in total. The mean H.S.S. score for the patients with loose beads was not different from the one of the patients without loose beads.

The quality of the radiograms, which were not always parallel to the prosthesis-bone surface, made it impossible to review bone-prosthesis contact or the appearance of radiolucent lines in the cemented prostheses. Narrowing of the joint space was seen on the full-leg length weight-bearing radiograms, seven times medially and four times laterally, a total of 9%. Because these radiograms were taken under full weightbearing, this narrowing was probably due to polyethylene wear. Lateral tracking of the patella was seen in

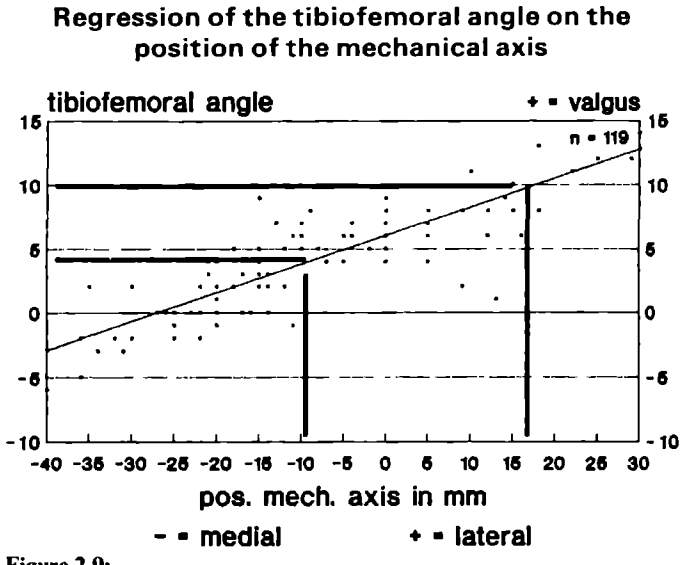


Figure 2.9:
Linear regression analysis of the tibiofemoral angle on the position of the mechanical axis

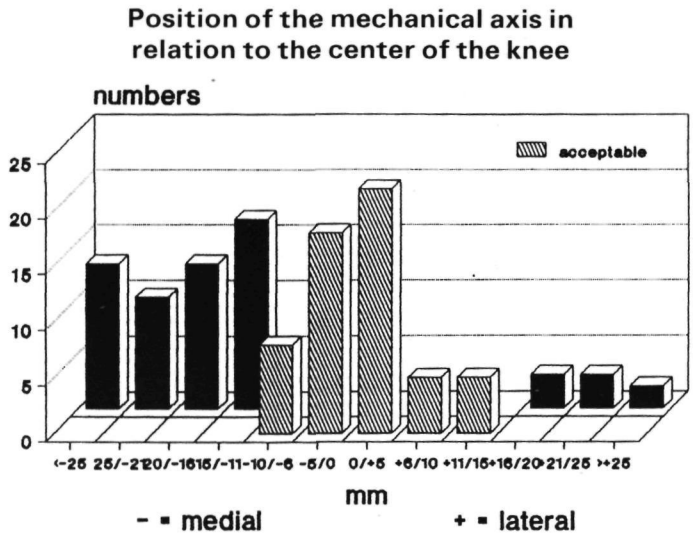


Figure 2.10:
Acceptable position of the mechanical axis in relation to the center of the knee

four cases and in three of them a lateral release was done. None of these patients suffered from anterior knee pain.

2.4 Complications and failures

Deep infections or late infections were not seen. There were 11 superficial wound healing

H.S.S. score and alignment

	good alignment	malalignment
	n = 23	n = 29
average	80	80.4
std. deviation	12.06	10.15

no significance

Table 2.2:
H.S.S. score in relation to alignment

problems and continuous passive motion was used in 8 of these patients C P M was used in 94 of the operated knees but with the chi-square test no influence of C P M on wound healing could be found (Table 2 3)
Femoral complications were not seen However, four tibial complications were recorded and all were serious In three cases there was no bony ingrowth and revision had to be performed within one year In one patient, the plateau was cemented, in another patient all components were revised and cemented, and in the third a hinged-type prosthesis was implanted The H S S. scores of these three patients were 76, 61 and 31 points, respectively In one case subsidence of the tibial plateau was seen This subsidence, in a 87 years old male, was located medial and anterior and resulted in an extreme genu varum with a radiological tibiofemoral angle of 6 degrees varus A possible explanation for this subsidence was the use of an excessively small tibial plateau None of the four patients with tibial plateau complications suffered from rheumatoid arthritis Probably the lack of mechanical stability of the tibial plateau was the reason for this high complication rate (Ryd, 1986, Volz et al , 1988).
Patella complications were quite frequent There was one fracture (which resulted in a patellectomy) and two loosenings, one cemented and one uncemented Neither of these two had to be revised because the complaints were minor There was one rupture of the patella tendon, and one patella alta Excessive wear of the patella component was seen once The polyethylene had disappeared completely and the metal backing of the patella could be felt gliding over the metal of the femoral component Clinically this patient had no anterior knee pain but had a synovitis and clicking of the patella

2.5 Discussion

The overall findings of this study, with 85% excellent or good results, can be compared to others In the literature, excellent or good results have been recorded in 85% to 97% of cases (Aglietti and Rinonapoli, 1984, Hungerford and Krackow, 1985, Ogata et al , 1988, Ranawat and Boachie-Adjei, 1988, Ranawat et al , 1989) The 'excellent' group in these studies was usually larger and the follow-up longer, but in the present study the average improvement of 40 H S S points in the score after operation compares well with the mean improvement of 41 points found by Insall (1979) and of 33 points found by Ritter et al (1984) The mean pre-operative scores in these studies were 43 and 48 points, respectively, and were higher than the average 40 points pre-operative score of the present study A low pre-operative score might have an adverse effect on the post-operative score, as evidenced by the fact that the present group with pre-operative H S S scores equal to or lower than 30 points produced excellent results in only 22% of the cases The average post-operative flexion range of 95 degrees is an acceptable result Compared to that of Hungerford (1983), who reported an average flexion range of 107 degrees, the result was poor, but other authors who studied the PCA total knee reported average flexion ranges between 90 degrees and 103 degrees (Bushuk et al , 1988, Matsui et al , 1988) The fact that malalignment did not influence the results must be explained by the

relatively short follow-up period, because other investigators, with longer follow-up periods, have found a clear relation between failure and poor alignment (Lotke and Ecker, 1977; Tew and Waugh, 1985; Moreland 1988; Windsor et al.,1989). This relationship could not be studied here, because there were only four cases with poor alignment and a follow-up period of more than five years.

Influence of the length of implantation on the H.S.S. score has not been studied often in the literature. The lower H.S.S. scores for the patient group with the longer follow-up period, as seen in this study, is not easily explained, because in fact the follow-up period is still short. Deterioration of the H.S.S. score was seen after a longer follow-up period (Goldberg et al., 1988) but it was not found in a study with a follow-up period similar to that of the present study (Aglietti and Rinonapoli, 1984). Of course, one can not conclude from the present study that the H.S.S. scores reduce gradually, post-operatively, only that patients with longer follow-up periods have, on the average, lower H.S.S. scores. It is quite likely that these results reflect the 'learning curve', in the sense that when the first PCA's were implanted, the lack of surgical experience produced suboptimal results.

The use of CPM did not influence the range of motion in our study. This agrees with the findings of Romness and Rand (1988), but Johnson (1990) noted an increased flexion range with the use of CPM. Wound healing problems were not related to the use of CPM, as was seen by other authors as well. The statement that CPM reduces the need for forced manipulation under anaesthesia (Coutts et al., 1983) was not confirmed by us. The number of patients (5.7%) requiring manipulation under anaesthesia was low in comparison to Insall et al. (1979), who found an indication for this procedure in 35% of cases. However, Ritter et al. (1984) reported a manipulation percentage of only 1.4%. The percentage of loose chrome-cobalt beads was higher than found by Rosenqvist et al. (1986). They found loose beads in 50% whereas they were seen in 65% of the cases in the

Superficial woundhealing problems and continuous passive motion

patients	wound problems	no wound problems
with C.P.M.	8	86
without C.P.M.	3	24
total	11	110

Table 2.3:
Superficial woundhealing problems and continuous passive motion

present study. In 1988 Howmedica improved the sintering technique for the porous coating bond (Howmedica R & D, 1988).
Eleven cases of unilateral joint-space narrowing (9%), indicating unilateral wear, is high for such a relatively short follow-up period, and was not described earlier. In 10 of the 11 cases, the mechanical axis of the leg passed through the narrowed compartment. Although this can not be definitely proven with the present material, it is suspected that there is a relationship between malalignment and increased unilateral wear (Engh, 1988).
The questions posed in the beginning of this Chapter, whether the surgical technique applied in the patient group investigated was adequate to produce good alignment, primary stability and clinical results on the mid-long term, can be partially answered based on the present study. The alignment achieved was definitely poor, that is to say, acceptable in less than half of the patients. Whether this is due to the inadequacy of the surgical instruments or to their use will be discussed in Chapter 5.
Primary stability, necessary to allow bone to grow into the porous coating, was certainly not sufficient in the case of the three prostheses which required revision in the first year. The cause for these failures was unclear. The question whether primary stability was sufficient in the other cases is difficult to answer, because bone ingrowth could not be evaluated on the radiograms. In any case, absence of pain at least indicates that it was acceptable.
Whether or not the clinical results are acceptable on the mid-long term is, of course, in the eye of the beholder. Eighty-five percent excellent or good H.S.S. scores is in the lowest range of 85 to 97% excellent or good results reported in the literature. Many of these reports originated from highly experienced clinics with a restricted number of surgeons involved. It is also obvious that the H.S.S. scoring system is not entirely objective and that so-called 'author' clinics may suffer from sub-conscious biases. Hence, the present results are certainly not bad.
Questions even more difficult to answer are whether the results can be improved with another prosthesis, better surgical procedures and experience, or with better indications. The first question can only be answered in a prospective follow-up study involving different prostheses and a standardized technique. Where the other two questions are concerned, very few significant relationships could be established. Of course, a clear indication as to the positive effect of experience was evident.
Finally, a question which can not be answered at all is whether the series will be successful on the longer term. Only time will tell, but the high percentage of unilateral joint narrowing is disturbing since it points to early occurrence of excessive wear. Whether this is the effect of prosthetic factors or of malalignment is investigated in the next two Chapters.

3. CHARACTERISTICS OF WEAR

3.1 Introduction

Polyethylene wear has always been a matter of concern in total joint replacement and especially in total knee replacement This is due particularly to the disgruent joint surfaces in the 'anatomic' (total condylar) prostheses, which have relatively small contact surfaces and high contact pressures In addition, the combined sliding and rolling knee-surface motions cause much more complex and severe dynamic, three-dimensional stress patterns in the polyethylene than those which occur, for instance, in the relatively simple configuration of the congruent, ball-in-socket hip joint As a result, wear is a much greater threat to the endurance of the tibial component of total knee replacement than the acetabular component of total hip replacement (Landy and Walker, 1988) Recently, severe clinical wear problems have been reported associated with the use of carbon-reinforced polyethylene as tibial plateau material (Wright et al, 1988), to the extent that this material is no longer used However, severe wear also occurs in normal Ultra-High Molecular Weight Poly-Ethylene (UHMWPE), and not all orthopaedic surgeons are aware of the seriousness of this problem The wear is not only a problem of long-term endurance, of course, but also of the biocompatibility of wear particles. These particles tend to create adverse tissue reactions and may provoke implant-interface loosening and bone resorption Seven different types of wear have been identified, as discussed by Hood et al (1983) *Surface deformation* is not a loss of material but a result of permanent deformation (cold flow) *Pitting* (or crater formation) occurs when small pieces of material are chipped-off from the surface, due to fatigue cracks in the material, slightly below the contact surface where the highest shear stresses in the material occur *Scratching* is a process of direct wear, whereby the small surface irregularities plough into the softer material *Burnishing* is a form of wear in which the softer material is polished by the harder one *Abrasion* is a more severe process of scratching, whereby the material is shredded *Three-body abrasion* is a process of grinding related to the presence of particles between the contact surfaces, such as acrylic cement A form of wear that is of particular interest here is *delamination,* in which a thin surface sheet of polyethylene separates from the deeper layers Wright et al (1988) found delamination only in carbon- reinforced UHMWPE This delamination was explained by insufficient bonding of the polyethylene and the carbon fibers during the molding process of manufacturing This made it less resistant to fatigue crack propagation than normal UHMWPE (Connelly et al , 1984) However, in a longer follow-up study of retrieved normal UHMWPE material by Landy and Walker (1988), delamination was also seen in 37% of the cases and it was related to subsurface cracks, cyclic loading of the material (Bartel et al 1986), and the presence of molding defects (Rose 1979)

Early gross failure of carbon-reinforced polyethylene components has also been described in some case reports (Dannenmaier, 1985, Wright et al , 1988) It was thought to be rare for normal UHMWPE and was only described once in a case report after four years

follow-up (Engh, 1988). However, it has recently been reported by several authors after primary PCA total knee replacements (Lindstrand et al., 1990, Tsao et al., 1991, Kilgus et al , 1991, Wright et al.,1992) Hence, it is not only a problem of carbon-reinforced polyethylene, but can also occur in UHMWPE knee prostheses

The direct causes of excessive wear are related to material characteristics of the bearing surfaces, their surface texture, the characteristics of the lubricant, the contact areas, load and surface motions For practical purposes, these causes can all be related to patient factors, surgical factors and prosthetic factors (design and material) These (four) factors are briefly discussed in the next section. In the remainder of this chapter, the prosthetic material factor is emphasized in particular. In a retrieval analysis of two PCA prostheses the prime causes of excessive wear will be identified.

3.2 Contributing factors

Of the *patient factors,* body weight and activity level have shown to be of influence (Hood et al. 1983), because they have an effect on loading magnitude and frequency Factors such as diagnosis (osteoathritis versus reumatoid arthritis), ambulatory status (ability to walk without a crutch, with one or two crutches, or with a walker), and age are less significantly related to wear (Landy and Walker, 1988, Mintz et al , 1991) Sex is not believed to be related to wear

Of the *surgical factors,* alignment has been mentioned as being of influence on polyethylene wear, but this has never been confirmed (Rose et al., 1984; Engh, 1988). It stands to reason that alignment has an effect on the load distribution over the lateral and medial compartments This effect will be discussed in Chapter 4 Another surgical factor of importance is the management of excessive acrylic cement When this is not properly removed, cement particles will migrate between the contact surfaces and provoke three-body abrasion Dramatic wear effects have been seen as a result of this mechanism in retrieval studies (Isaac et al , 1992) Finally, the spacing of the bone cuts is of influence. If the spacing is too narrow, the ligament and capsule structures will compress the components, thereby increasing the contact forces

Of the *design factors,* the retention of the posterior cruciate ligament (PCL), the thickness of the polyethylene component, and the shapes of the bearing surfaces are of particular interest Retention of the PCL , as in the PCA prosthesis, has the advantage of maintaining the femoral rollback in flexion, this provides normal muscle function and flexion motion (Andriacchi, 1986) It is also responsible for lower shear forces and rocking moments, but has the disadvantage of producing higher contact forces, which might lead to more wear (Soudry et al , 1986) Nevertheless, Andriacchi and Galante (1988) believe that the increase of contact force caused by PCL retention has little or no impact on wear of the polyethylene

The thickness of the polyethylene is another design factor that has influence on the contact stress Wright and Bartel (1986) have shown that the contact stress increases rapidly when the thickness of the polyethylene is insufficient The contact stress depends

on the extent of the contact area, which is enlarged during loading due to the deformation of the polyethylene. The deformability reduces when the polyethylene gets thinner This effect is particularly progressive when the thickness is less than 8 mm Beyond 8 mm it rapidly diminishes. This is why Bartel (1986) advised using a polyethylene part of at least 8 mm thick. To achieve this for the modern metal backed tibial plateaus, like the PCA, these components should be at least 10 mm thick because the metal part takes 2 to 3 mm of thickness

The bearing surfaces have an influence on the size and shape of the contact areas, and on the constraints of the joint A large contact area will lead to lower contact stresses than a small contact area. The shapes of the contact areas can roughly be devided in two groups, a line type and a point type contact area. Bartel et al. (1986) have shown, using finite-element analysis, that the largest compressive stress inside the poyethylene occurs at the centre of the contact area The maximum tensile stress is located at the edge of the contact area. This means, for the line-contact type prosthesis, that the maximum tensile and maximum compressive stresses are very close to each other Hence, a very high stress gradient occurs, which results in full stress reversal in the material during knee motion Because of the posterior cruciate retention (as in most modern prostheses), and low constraints of the bearing surfaces, the femoral rollback mechanism is still intact, and this leads to a posterior/anterior shift of the contact area over the surface of the tibial plateau This rapid variation of tensile and compressive stresses is a factor in the propagation of fatigue cracks (Connelly et al., 1984) The contact area of the primary PCA knee prosthesis can be qualified as a line contact. This line contact is caused by the flat surface of the tibial plateau and the cylinder-shaped femoral condyles

The *material factors* include the molecular weight of the polyethylene and the structure of the material, as it develops depending on the production technology It has been assumed that a high molecular weight of the polyethylene is a factor in the resistence to wear It can be measured by the intrinsic viscosity method (Rose et al , 1980) During the production process, the polyethylene powder is melted under compression It is essential that the temperature is not too high, otherwise degradation of the polymer chains can occur, which reduces the molecular weight (Rose et al., 1979). When the moulding process has not been performed correctly, insufficient fusion is seen between the polyethylene particles. These fusion defects are related to a form of wear called pitting or crater formation (Rose et al , 1979) The moulding defects can conglomerate and form subsurface microcracks, which may lead to delamination. The structure of the polyethylene can be investigated by light microscopy.

The chemical structure of polyethylene which gives the least wear is an ultra high molecular weight material with cross-linked molecules and a crystallinity less than 50% (Rose et al., 1980). Polyethylene with such a structure has a relatively low elastic modulus This is important, because a low elastic modulus will cause less contact stress, owing to contact deformation (Wright and Bartel, 1986), for the same reason as large thickness does A surface treatment of the polyethylene as given by the manufacturer for the PCA primary total knee prosthesis, by which heat is supplied in order to create a smooth surface, can cause a lower molecular weight at the surface, and change the chemical structure of

the polyethylene. The crystallinity can be investigated by differential scanning calorimetry (DSC).

3.3 Retrieval cases

Two PCA total knees were retrieved because of excessive wear at 3 years follow-up. The molecular weight, the structure and the crystallinity of the polyethylene were studied.

Case 1
A 55 year old farmer with a body weight of 90 kg and a length of 173 cm suffered from osteoarthritis of his left knee after a medial meniscectomy. A PCA primary total knee prosthesis was implanted uncemented and a 7mm thick tibial plateau was used. One year post-operatively the HSS knee rating score (Insall et al. 1976) was 93 points and the alignment was perfect on the full-leg length, weight-bearing radiograms. At two years follow-up there was no change, but at three years the HSS score dropped to 59 points and there was severe synovitis. On the weight-bearing radiogram the medial joint space had disappeared completely and there was bone resorption at the edges of the prosthesis (Fig. 3.1). The mechanical axis (line from the centre of the hip to the centre of the ankle) was now in the medial joint space, at 2.3 cm from the centre of the knee.
At revision the destroyed tibial component had to be removed and a complete synovectomy was necessary. The polyethylene showed massive delamination and material fracture (Fig. 3.2). Because of the bone resorbed, a new tibial bone cut was made and an 11 mm thick component implanted.

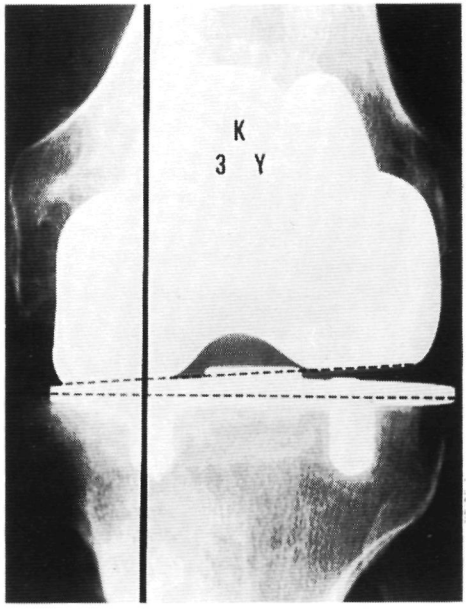
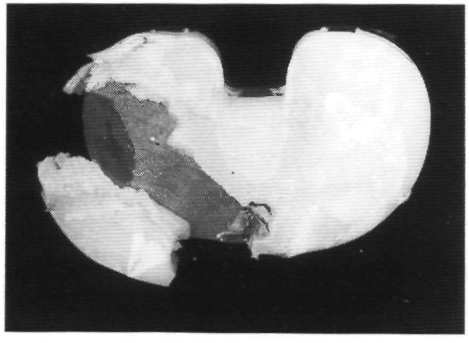


Figure 3.1:
Detail of full-leg length weight-bearing radiogram of patient one at 3 years follow-up

Figure 3.2:
The tibial component of patient one at 3 years follow-up showing massive delamination



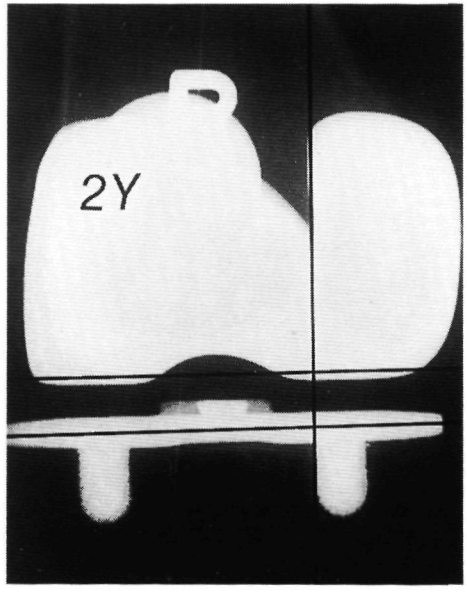


Figure 3.3:
Detail of full-leg length weight-bearing radiogram of patient two at 2 years follow-up

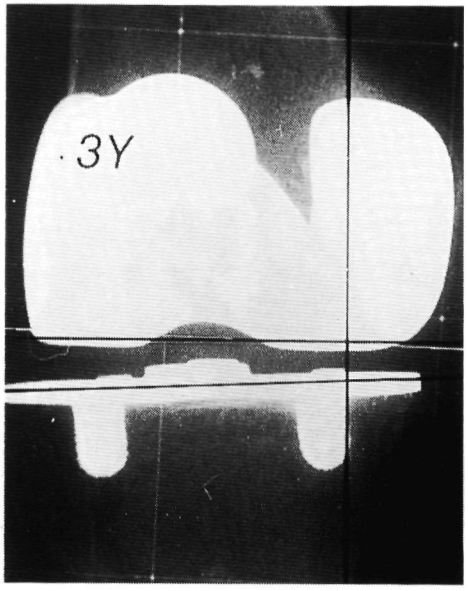


Figure 3.4:
Detail of full-leg length weight-bearing radiogram of patient two at 3 years follow-up

Case 2

A 77 year old woman with a body weight of 95 kg and a length of 161 cm suffered from arthritis of her right knee. An uncemented PCA total knee was implanted with a tibial component of 9mm. At 1 year follow-up the result was excellent, with an HSS score of 93 points. On the full-leg length radiogram, shown in detail in Figure 3.3, the mechanical axis was located in the medial compartment of the knee, 1.5 cm from the centre. One year later she suffered from mild anterior knee pain, but the rating score still showed 86 points. On the radiograms loosening of the patella was evident. Three years after surgery, the HSS score dropped to 63 points. There was serious global knee pain and synovitis of the joint. Narrowing of the medial joint space was seen on the full-leg length weight-bearing radiogram (detail Fig. 3.4), combined with medial shifting of the mechanical axis from 1.5 to 2.5 cm away from the centre of the knee. There were signs of loosening of the patella.

At revision new tibial and patellar components were cemented, combined with a synovectomy. The polyethylene of the tibia showed severe signs of wear, especially delamination.

3.4 Polyethylene analysis

Molecular weight

An attempt was made to measure the polyethylene molecular weight of the two retrieved specimens, using the intrinsic viscosity method, but this was not possible because the

material was not soluble in decaline. This means that either cross-linked molecules were present or that the molecular weight was over 6 x 10^6. From the viewpoint of wear, both cross-linking and high molecular weight are advantageous.

Structure

Sections were taken from a delaminated area and from a still intact part of the tibial component of the second patient, and from an unused tibial component of the primary PCA series as a reference. These sections, 7 μm thick perpendicular to the surface, were examined by light microscopy. The original polyethylene granules could be identified in all three samples. In the retrieved material the bounderies of the granules were even clearer than in the reference case. This was evident in particular in the subsurface of the material (Fig. 3.6). In the reference sections a well moulded surface layer of 300 μm, without clear boundaries between the PE particles (the same thickness as the delaminated layer) was found, based on a poorly moulded layer of 600 μm thick, with clear PE boundaries. Deeper still the moulding was acceptable (Fig. 3.5). This difference in morphology of the layers of the material can only be explained by the surface treatment, mentioned above. In the macroscopically intact part of the worn component, delamina-

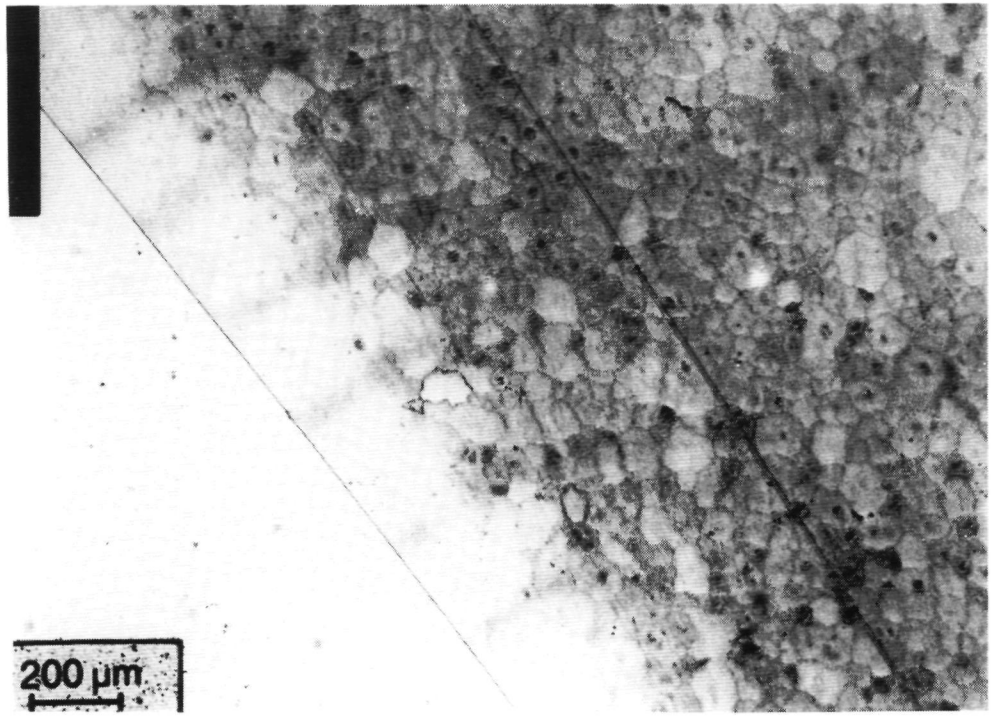


Figure 3.5:
Light microscopy view perpendicular to the surface of the reference tibial component

tion was seen directly under the surface layer, coinciding with the boundary of the surface layer (Fig. 3.6). This clearly suggests that the surface heat treatment creates a weak boundary between the surface layer and the deeper ones, which gives rise to failure (delamination) under loading.

Crystallinity

With differential scanning calorimetry the polyethylene is melted, and the melting temperature and the amount of energy required to melt the material are recorded. With these data the crystallinity (the percentage of molecules which formed a crystal structure) can be calculated, because the amount of energy (J/g) for 100% crystallinity of pure PE is known (293 J/g). The material is melted twice. The first heating curve is affected by earlier thermal treatments in the production process. In the second heating curve this effect is eliminated and the original structure is evaluated. Samples for the tests were taken from the intact weight-bearing surfaces and interior parts of the two retrieved components, a delaminated portion from the first patient, a non-weight-bearing part of the surface from the second patient, and the surface and interior of an unused component as references. The results are shown in Table 3.1. The low crystallinity of the dela-

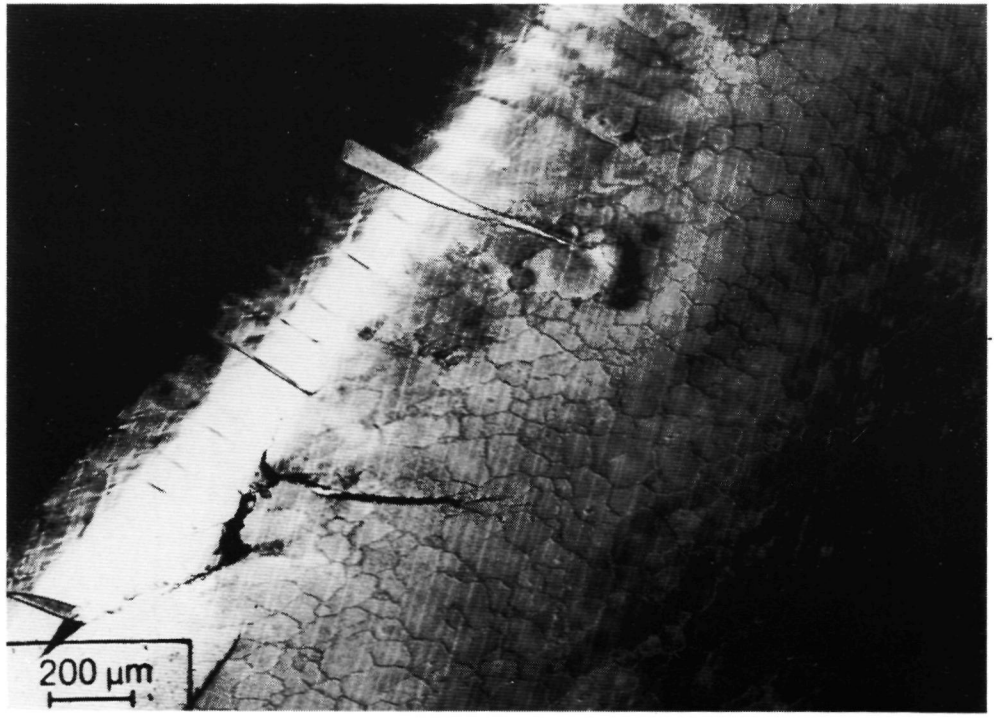


Figure 3.6:
Light microscopy view perpendicular to the surface of a still intact part of the tibial component of patient two

minated part must be explained by degradation of the molecules due to wear In the samples from the second patient and in the reference sample, no differences were seen in the first heating curve between the non-weight-bearing surface and the interior. This means that the thermal treatment applied to the surface did affect the total mass of the polyethylene and not only the surface. The slightly higher crystallinity of the weight-bearing surface of the second patient must be explained by a better structure of the crystals themselves under the influence of loading Another interesting point is that in all samples the crystallinity found in the first heating curve was higher than that in the second curve From this it can be concluded that Howmedica, who used a polyethylene with a rather high crystallinity, as shown in the results of the second heating curve (> 50%) in Table 3.1, increased this crystallinity further (and, indirectly, the elastic modulus) by their surface treatment

3.5 Discussion

Wear particles cause synovitis, and the inflammatory reaction is characterised by a histiocytic and giant-cell reaction It can also lead to bone resorption at the edges of the prosthesis (Pizzoferrato, 1979) and to loosening of the artifical joint on the longer term (Amstutz et al , 1992) In addition, excessive wear can cause complete destruction of the tibial plateau, and a failure of the treatment

The diagnosis of excessive wear in an artificial knee joint is not always easy, but it must be suspected in all patients with synovitis and a diminishing clinical rating score Early diagnosis is very important for the modern modular types of prosthesis, because synovectomy and replacement of the polyethylene part may prove to be a sufficient treatment

Crystallinity of UHMWPE in %

	first heating curve	sec. heating curve
patient one		
weightbearing surface	70 %	59 %
laminate	55 %	54 %
interior	70 %	62 %
patient two		
weightbearing surface	68 %	64 %
nonweightb. surface	63 %	58 %
interior	63 %	60 %
reference		
surface and interior	58 %	54 %

Table 3.1:
Crystallinity of the polyethylene in percentage

(Uchida et al., 1980). In the first patient excessive wear could be clearly diagnosed on the weight-bearing radiogram; the medial joint space had disappeared completely. In the second patient the diagnosis was not particularly obvious. There was synovitis, a reduction in the H.S.S. score, and radiographic loosening of the patella. The diagnosis became only clear because full-leg length, weight-bearing radiograms were made at follow-up. By reconstructing the mechanical axis on these radiograms, a gradual shift was found (Figs. 3.3 and 3.4). This shift was caused by narrowing of the medial joint space, which could have been easily overlooked if the mechanical axis had not been drawn on the radiograms and compared with older radiograms. This shows the importance of full-leg length, weight-bearing radiograms at follow-up of a total knee replacement.

Reviewing the four wear related factors for total knee replacements it is clear that all prostheses with a small contact area (particularly line-type areas) and a thin polyethylene part on a metal-backed plateau are susceptable to excessive wear. Recent publications, however, showed that early failure of the polyethylene component occurs particularly in the PCA primary prostheses. The reason for these failures is not only the thinness of the polyethylene, or the small line-type contact area, but also the quality of the polyethylene and the surface treatment given to create a smooth surface. The polyethylene, probably of sufficient molecular weight, proved not to be well moulded and had a relatively high crystallinity, hence a relatively high elastic modulus. As a result, the deformability of the polyethylene is relatively low, hence the contact surface under loading is reduced, which increases the contact pressure and the rate of wear. The crystallinity is even further increased by the surface heat treatment given to the components at manufacturing. Another effect of this heat treatment is that it creates nonuniform structural properties between the superficial and the deeper layers of polyethylene, hence a boundary (or 'interface') is created under the surface, which is weaker than the material itself. This interface occurs precisely there, where the maximal shear stresses in the material under the contact area occur under loading. Hence, dynamic loading can easily provoke fatigue failure and delamination.

It can be concluded that polyethylene quality is extremely critical for the total-condylar type knee prostheses, particularly in the case of small contact areas and thin plateaus. There is little room for error, hence companies should continuously test their production processes and material qualities. 'Improvements' or innovations should only be introduced after rigorous pre-clinical testing in joint simulators and subsequent controlled, limited clinical trials.

In addition, knee-replacement patients should be seen frequently post-operatively, particularly on the longer term, to check for excessive wear, in order to be able to take timely measures, before wear particles create a disaster. During each follow-up check, full-leg, weight bearing radiograms must be made and measured to monitor shifts in the mechanical leg axis.

4. ALIGNMENT AND WEAR

4.1 Introduction

From several clinical studies it became clear that achieving good alignment in total knee surgery was difficult (Lotke and Ecker, 1977, Matsui et al , 1988) In the patient group described in Chapter 2 malalignment was found in about 50% of cases. Although malalignment has been mentioned as one of the factors that cause accelerated polyethylene wear, this was never well documented, and the relationship has been denied by some authors (Engh, 1988, Lindstrand et al., 1990, Mintz et al , 1991) In several studies, in which knee joint simulators or other wear-testing machines have been used, relationships between wear and load, sliding distance, molecular weight of the polyethylene and its thickness were found (Rostoker and Galante, 1979, Rose et al., 1980, Wright and Bartel, 1986, Walker et al , 1991) The effects of malalignment, however, have not been investigated.

The mechanical axis of the leg (center hip to center ankle) is the axis by which the forces are transmitted through the leg in the relaxed double-leg stance When this axis runs through the center of the knee, an equal load can be expected to be carried by the medial and lateral compartments of this joint in this situation. But when the axis lies in the medial or the lateral compartment, the part of the joint concerned will carry more load than the contralateral compartment (Rozing, 1976) Because a relation between wear and load exists, it stands to reason that malalignment causes accelerated wear in the overloaded compartment and decelerated wear in the underloaded one Nevertheless, this relation is not all that trivial, since plateau deformation and kinematic parameters play a role as well The purpose of the study described in this Chapter was to investigate whether the relation between wear and malalignment could be confirmed.

This problem could not be solved based on the patient material presented in Chapter 2 In fact, the study of in vivo wear in a reasonable time period is next to impossible First of all, roentgen measurements of wear are relatively imprecise, hence a considerable amount is required before this can be established with significance Secondly, a number of other factors, such as patient weight and activity level, play a role as well Hence, a large patient group would have to be followed for a long period of time to establish a significant relationship between wear and alignment

In order to investigate the relation between wear and alignment in this study, central and progressively eccentric loading of the prostheses were studied in a knee joint simulator, in order to find out whether there is a relation and to see which degree of malalignment is still acceptable from a wear point of view The loading axis of the machine can be compared to the mechanical axis of the leg (line center hip to center ankle). By shifting the loading axis of the simulator, the influence of alignment on polyethylene wear can be studied

4.2 Methods and Material

In this study, the knee motion simulator of the University of Twente, Division of Biomechanical Engineering, was used (Bosman et al , 1979). This machine was especially designed for use in studies concerning problems of the human knee. Because of the flexibility of its design it is possible to produce excentric loading of the prostheses This simulator produces a relative movement of the femur on the tibia in flexion and extension in the sagittal plane with realistic instantaneous change of the centre of rotation A simultaneous rotation of the tibia around its own axis relative to the femur also takes place The motion characteristics are based on the work of Levens (1948) and Steindler (1955) The applied forces during the walking cycle are conform those described by Morrison (1970) In Fig 4 1 a schematic diagram of the simulator shows a rigid main frame indicated by the roman number I, a pivotting frame II to which the femoral holder IV is fixed. The tibial holder III, fixed to the main frame, can rotate around its own axis The load is applied by a pneumatic cylinder 5. This simulator produces natural motion characteristics of the knee during gait, including femoral rollback, flexion (70°), extension (3°) and rotation of the tibia as was also described by Kettelkamp (1970). The applied force has a maximum of 2400 N just before toe-off, which corresponds with approximately 3 times body weight

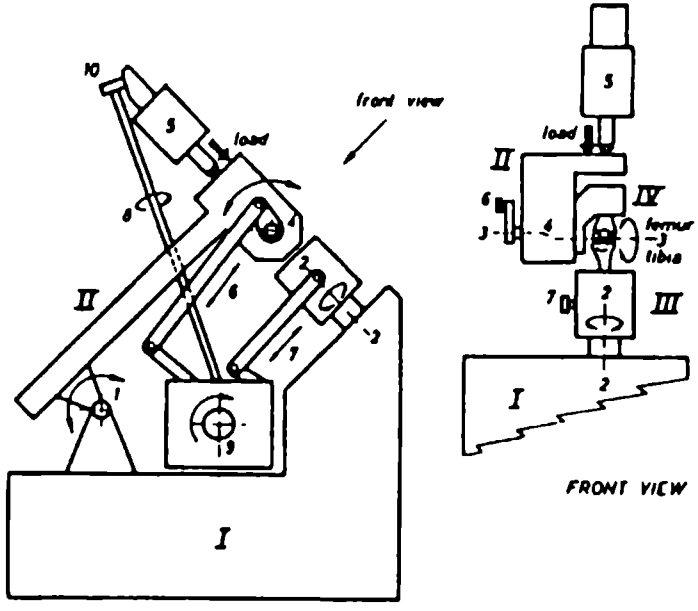


Figure 4.1:
Schematic diagram of the knee jointsimulator

PCA (porous coated anatomic) modular prostheses were used for the tests. This prosthesis is a successor to the PCA primary prosthesis (described in Chapter 1) and can be seen as a representative of a modern, low constrained, high contact stress total-condylar type prosthesis. Changes in comparison to the PCA primary prosthesis are a larger choice of components for a better individual fit, a modular system for the tibial component with interchangeable polyethylene inserts and an increased, more circular contact area in order to reduce the contact stress on the polyethylene (Howmedica, 1988; Hungerford et al., 1988). There were five tests performed with the PCA modular prosthesis with the 9 mm thick tibial component placed in the knee joint simulator.

The prosthesis was centrally loaded once, but in the other four tests the loading axis was placed 1 and 2 cm medially and laterally, respectively, to the center of the prosthesis (Table 4.1). All prostheses were tested for 150,000 cycles, at a frequency of 25 steps per minute, which is about half the normal walking speed. The 150,000 cycles were chosen based on the work of Wright (as cited by Peterson et al., 1988) and should be similar to a clinical use of 3 years for an average patient.

An environmental chamber filled with bovine serum surrounded the prostheses, which was kept at 37°C . To prevent bacterial overgrowth, tetracycline was added to the solution. This bovine serum produces a type of wear of the polyethylene similar to that of synovial fluid (McKellog et al., 1978). Wear was measured with the dimensional method, whereby the shape of the worn plateau is compared to its original shape. This enables location of the wear produced, but has the disadvantage that it also measures the plastic deformation of the material under load (cold flow). In this study surface profile scans were made of the plateaus by placing a 0.5 mm thick tracer on the surface of the polyethylene and measuring the displacements of the tracer. The surface was scanned from

Position of the loading axis

loading case	pos. loading axis
1 C	central
2 M1	1 cm medial
3 M2	2 cm medial
4 L1	1 cm lateral
5 L2	2 cm lateral

Table 4.1:
List of the position of the loading axis

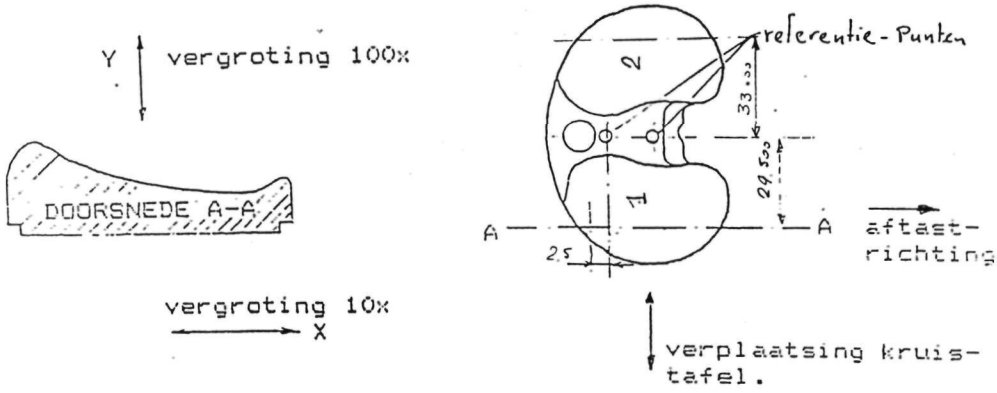


Figure 4.2:
Schematic drawing of the tibial component indicating the reference points and the direction of scanning

front to back and from the periphery to the centre (Fig. 4.2). The lines produced, with an interval of 0.5 mm, were drawn on paper, blue for the scan before the test and red for the one after the test (Fig. 4.3). Reference points placed in the centre of the prostheses ena-

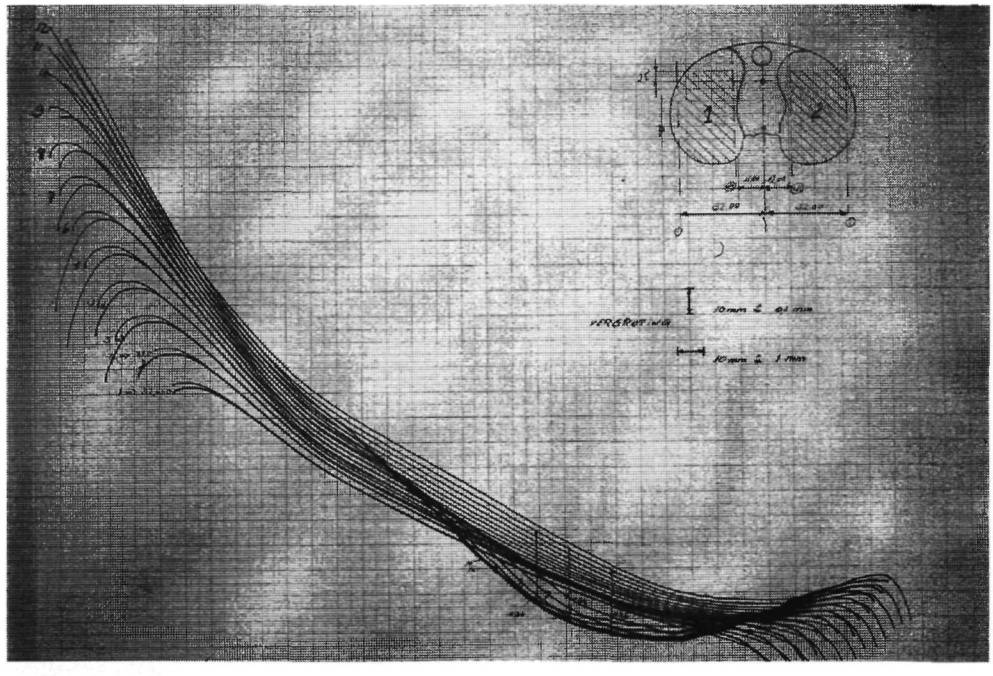


Figure 4.3:
Surface profile scan of the medial surface of loading case M2, lines before and after the test

bled comparisons of the profile scans of the different prostheses with each other. In this way it is possible to compare the shapes of all the unused prostheses to see if they were reproducibly manufactured. A contact tracer Contracer (type CB 41) from Mitutoyo was used, which has an accuracy of ± 0.02 mm.

Another important parameter to characterize wear is surface roughness, which was measured on a Perthen S5P machine before and after the testing program. With this machine, which uses a more refined method than the Contracer, the ridges on the surface are registered and their average distances (center line average, c.l.a.) are calculated in µm (Fig. 4.4).

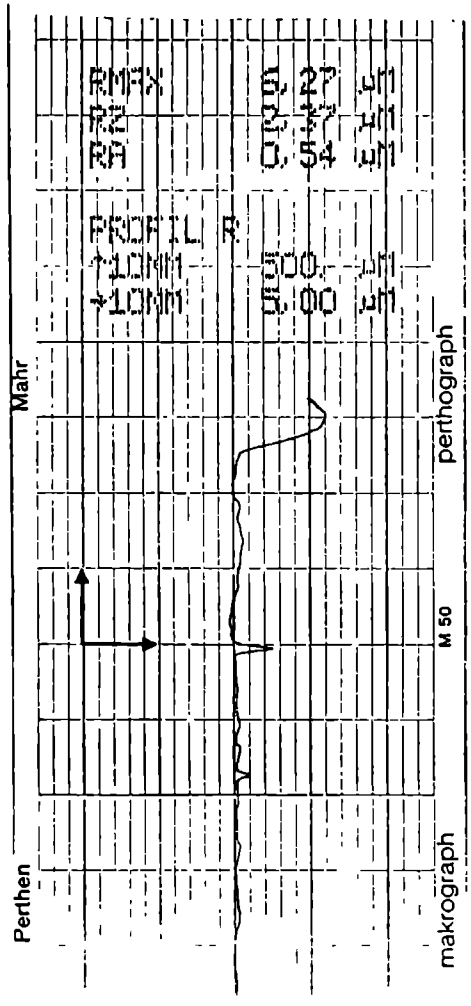


Figure 4.4:
Example of the surface roughness of the medial surface of case L2 before the test

The surface contact area, another wear parameter, was also determined. A Fuji pressure sensitive film was used for the registration of the contact areas before and after the loading tests. The pressure sensitive film was placed between the tibial and femoral components of the prostheses in the knee joint simulator under a flexion angle of 10 degrees and during a period of 30 seconds a force of 2400 N was applied. The prints were made for all specimens, under the same loading conditions as during the wear tests, that is to say, for variable loading axes, central, medial and lateral, before and after the wear tests. Under central loading conditions a print of the contact area of a medium size PCA primary prosthesis was made for registration of the size and shape of this prosthesis in comparison with that of the PCA modular. The prints were digitized and the areas measured (reproducibilty 1-1.5%). Because the color intensity of the film is related to the contact pressure, the pressure patterns could also be studied.
Finally, the surface of the 2 cm laterally loaded insert was investigated by light microscopy and scanning electron microscopy (SEM type Philips 505). This was done in order to study the surface damage caused by the test and to see if there were microcracks in the polyethylene. Sections of 7 μm thickness perpendicular to the surface of the weightbea ring and non weightbearing areas of this insert were investigated by light microscopy. In this way the morphology of the polyethylene becomes visible. The effect of a surface treatment and the quality of the molding process can be studied (as described in Chapter 3). Differential scanning calorimetry (Perkin Elmer type DSC-7) was performed on the surface (weight-bearing and non weight-bearing) and the interior of the insert, in order to study the crystallinity and the effect of the surface treatments of the polyethylene during manufacturing (as described in Chapter 3).

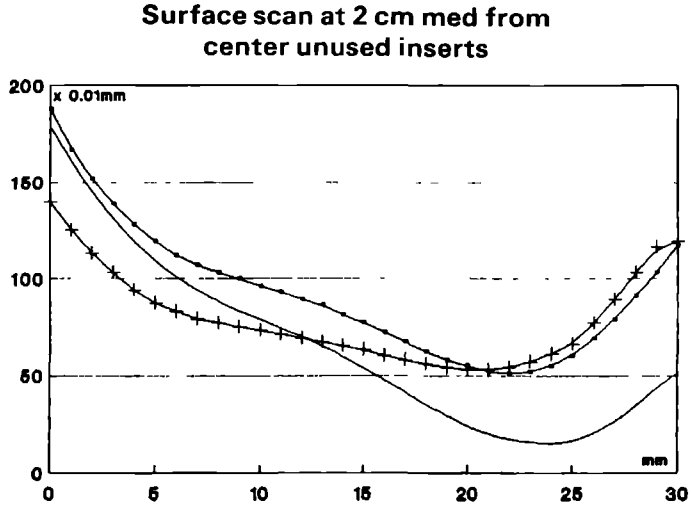


Figure 4.5:
surface profile scan at 2 cm medial from the center for 3 different unused inserts

Max. loss of height of the surface in mm

loading case	medial	lateral
C	0.05	0.04
M1	0.13	0.02
M2	0.28	0.01
L1	0.06	0.16
L2	0.05	0.36

Table 4.2:
Maximum loss of height of the surface in mm

4.3 Results

Visual inspection of the inserts showed little wear. Of the seven forms of wear defined (described in Chapter 3), only wear burnishing was present (Rostoker et al., 1978). The surface profile scans showed the most loss of height at 2 cm medial and at 2.5 cm lateral from the center of the prostheses This is why the surface profile lines at 2 cm medial and 2.5 cm lateral were taken as standards for the amount of wear for the medial and lateral

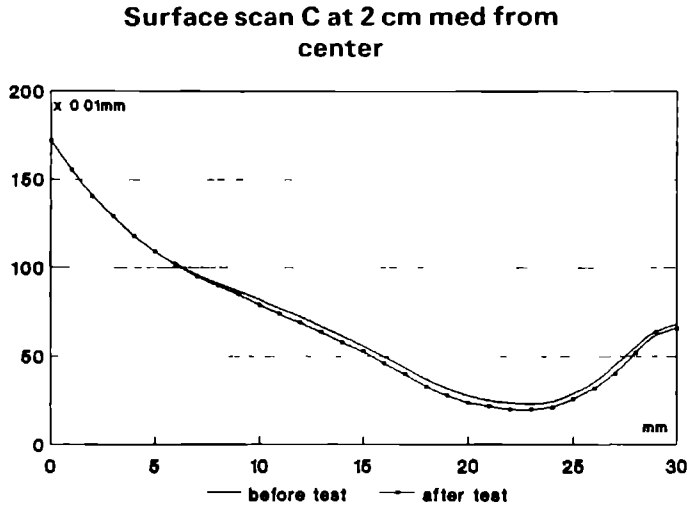


Figure 4.6:
Surface profile scan of loading case C at 2 cm from the center

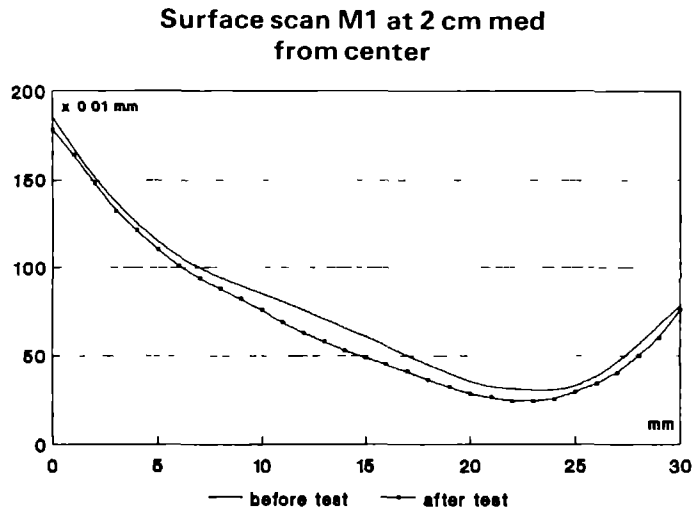


Figure 4.7:
Surface profile scan of loading case M1 at 2 cm from the center

compartments. First the unused inserts were compared and differences in the shapes of the surfaces were found. This is shown in Fig. 4.5, using an example taken from the medial side. The maximal measured difference between the surface profile lines at 2 5 cm lateral from the center showed to be 0.52 mm, and the profile lines at 2 cm medial from the center showed a maximal difference of 0.72 mm.

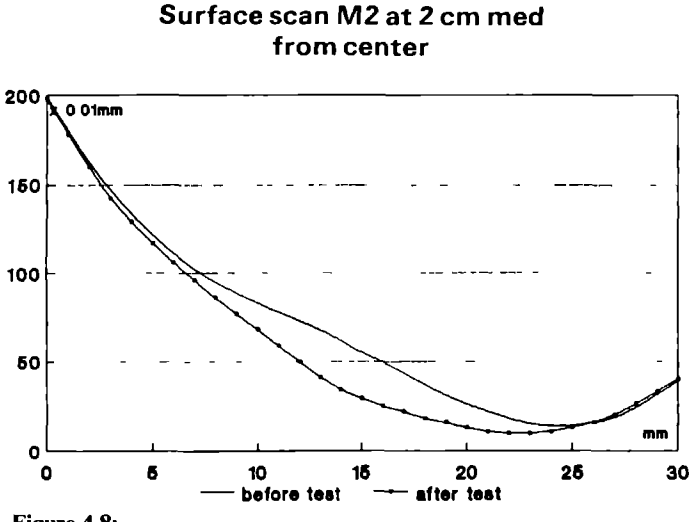


Figure 4.8:
Surface profile scan of loading case M2 at 2 cm from the center

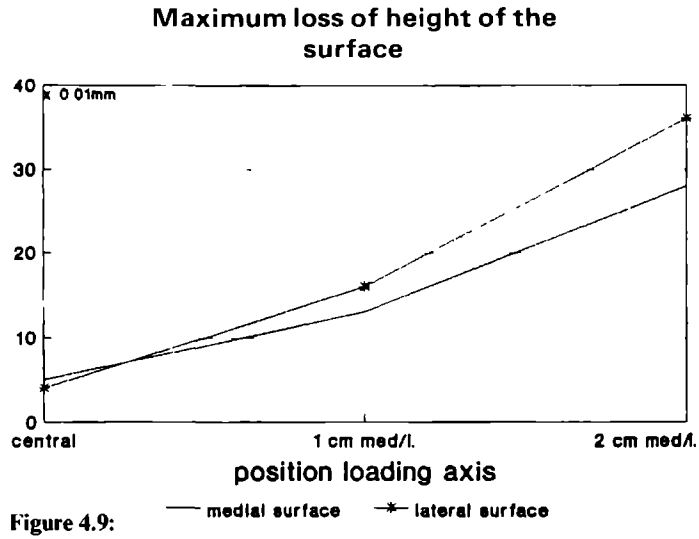


Figure 4.9:
Diagram of the maximum loss of height of the surfaces

The amounts of wear caused by the tests with the different loading conditions, measured as a loss of height of the surfaces at 2 cm medially and 2.5 cm laterally from the centers of the inserts, are listed in Table 4.2. The surface profile lines on the medial side showed progressive loss of height for the central, 1 and 2 cm medially loaded prosthesis (Figs. 4.6, 4.7, 4.8)). On the lateral side, similar patterns were seen, but here more loss of height

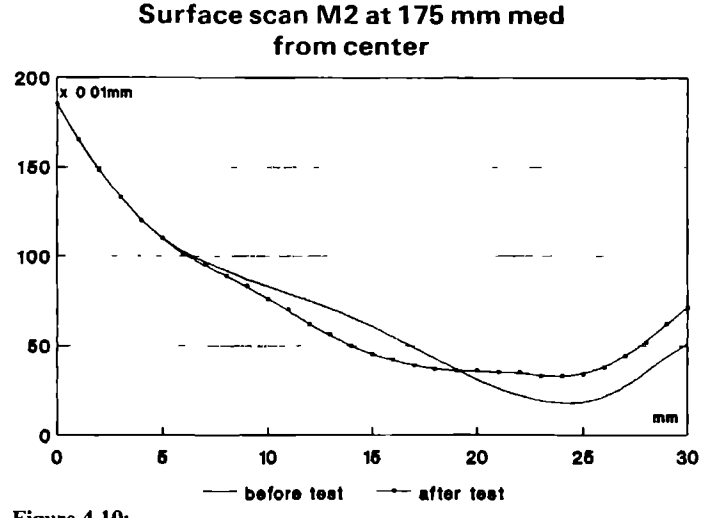


Figure 4.10:
Surface profile scan of loading case M2 at 1.75 cm from the center

Surface roughness in um
(centre-line-average)

loading case	medial surface (std. dev.) before loading	medial surface (std. dev.) after loading	lateral surface (std. dev.) before loading	lateral surface (std. dev.) after loading
C	0.19(0.04)	0.38(0.14)	0.20(0.05)	0.78(0.46)
M1	0.36(0.31)	0.64(0.28)	0.28(0.26)	0.96(0.23)
M2	0.25(0.01)	0.86(0.36)	0.25(0.03)	----
L1	0.18(0.04)	0.99(0.02)	0.14(0.04)	0.64(0.30)
L2	0.15(0.02)	0.76(0.31)	0.29(0.11)	1.19(0.07)

Table 4.3:
Surface roughness measured as center-line-average (Ra) in um

was evident (Fig. 4.9). Some cold flow was seen, especially at the dorsal side of the 2 cm medially loaded prosthesis, at 1.75 cm from the center of the knee (Fig. 4.10).

Figure 4.11:
Contact area of loading case L2 before and after the test
Object 1 = the lateral contact area
Object 2 = the medial contact area

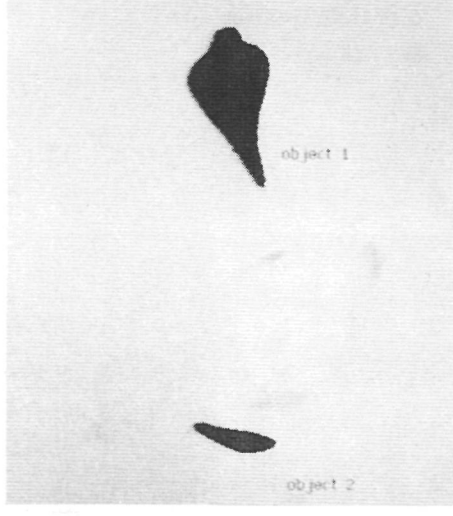
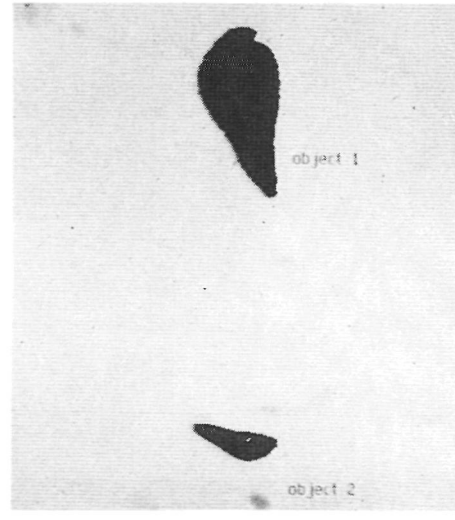


Figure 4.12:
Color intensity of the lateral contact area of loading case L2 before and after the test
Object 1 = the lateral contact area
Object 2 = the medial contact area



Surface area in square mm²

loading case	med. surface before\after\ loading		%	lat. surface before\after\ loading		%	total before\after\ loading		%
C	59	74	25%	52	68	30%	111	142	28%
M1	82	89	9%	21	29	38%	103	118	15%
M2	98	107	9%	5	24	380%	103	131	27%
L1	59	54	-9%	72	83	15%	131	137	5%
L2	14	18	28%	75	93	24%	89	111	25%

Table 4.4:
Surface measured in square mm before and after the test

Figure 4.12:
Color intensity of the lateral contact area of loading case L2 before and after the test

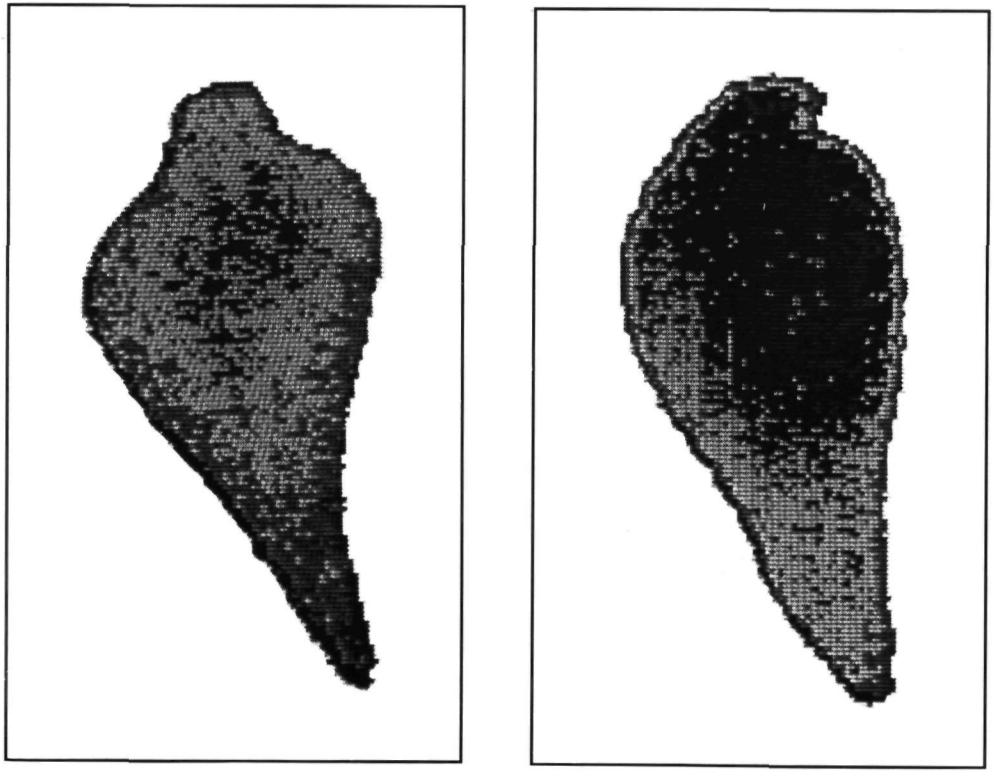


Figure 4.13:
Scanning electron microscopy of the lateral surface of loading case L2

The surface roughness showed an increase in all cases (Table 4.3). This increase was highly dependent on the eccentricity of the load. Higher values were found at the lateral surface, although the standard deviations were large. The roughness of the damaged lateral side of the M2 loading case could not be measured because of technical difficulties. It is interesting to see that the smoothness of the individual prostheses before the tests were not equal. One had a much higher surface roughness (tests M1) but again there was a wide standard deviation (Table 4.3).
An example of surface shapes determined with the Fuji film is given in Fig. 4.11 for the L2 loading case before and after the test. The results of the contact area measurements are shown in Table 4.4. In all cases there was an increase of the total area, most predominantly at the lateral side. Comparing the contact area of the medial surface (for the central, 1 and 2 cm medially loaded prostheses) with the lateral surface (for the central, 1 and 2 cm laterally loaded prostheses), a smaller contact area was found on the lateral side in all three cases. The shapes of the unused polyethylene inserts showed to have a direct influence on the size of the contact area, even though the differences on the surface profile scans were less then 1 mm. For a technical reason, one test had to be repeated, but this made it possible to compare the surface area of two different inserts under the same loading conditions. A difference of 15% in the size of the surface area was found on the lateral side but the difference was only a few percent on the medial side. This influences the contact pressure, which is directly related to polyethylene wear (Rostoker and Galante, 1979).
The pressure diagrams showed an increase in the color intensity of the Fuji film (Fig. 4.12), hence in pressure, in all but one case (L1). Because there was also an increase of

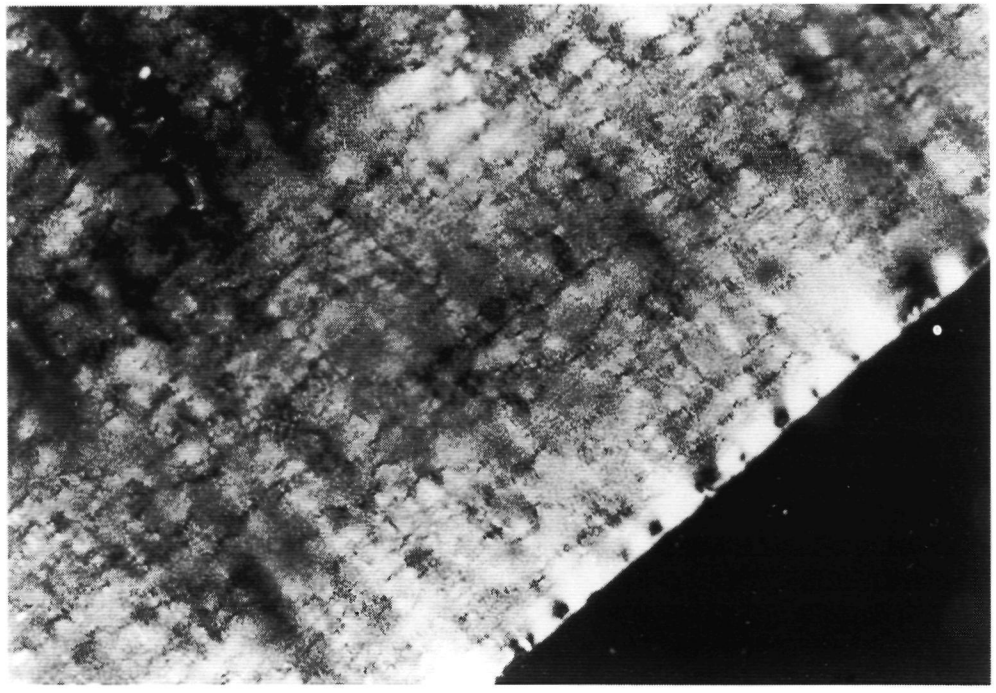


Figure 4.14:
Light microscopy view perpendicular to the surface of the weight bearing area of loading case L2

the contact area, this finding could not be explained by a higher contact stress.
With the introduction of the modular type PCA total knee replacement, which is available in the Netherlands since 1989, the contact area has changed in a more circular area as shown in Fig. 4.11. The surface areas of the old and the new model were measured by digitizing the Fuji film prints. The medial area was similar for both models (58.13 square mm for the new and 61.57 for the old one), but the lateral area of the old model was larger (72.21 versus 44.75 square mm.). Analyzing the pressure patterns by comparing the color intensity of the Fuji films, the maximum contact stress showed to be higher for the old model, both on the medial and the lateral contact sides in spite of a larger contact area laterally for the old model, which can only be explained by differences in local surface texture. The company which produces the plateaus writes in its brochure that the contact areas in the new modular prosthesis are larger and more circular shaped in comparison with the smaller, line-shaped areas in the old primary one. The second aspect was confirmed here, but a larger area was not measured. This may be due, however, to a difference in sizes, because the size-system of both prostheses are not fully compatible.
Light microscopy of the lateral surface of the plateau subjected to loading case L2 showed some deformation in the form of folds over the surface. Scanning electron microscopy revealed the same pattern but also showed some microcracks between the folds (Fig.

4.13). In the perpendicular section of case M2 a thin surface layer of 50 μm was seen, followed by a fairly good molded layer of the polyethylene, although the boundaries of the granule could still be recognized (Fig. 4.14). The crystallinity of the material calculated from the results of the differential scanning calorimetry (DSC) was low (49%) for the surface layer and the inner section of the prostheses in the second heating curve. In the first heating curve a slightly higher crystallinity was found. The first heating curve of the surface showed a small second peak in the unloaded area, and this peak increased clearly in the loaded area of the prostheses. This second peak in the DSC curve was probably caused by a surface treatment performed by the manufacturer. This increase must have been caused by heat produced during the wear test (Davidson et al., 1987; 1988).

4.4 Discussion and conclusions

In earlier joint-simulator studies the amount of wear was measured by weighing the tibial components before and after the tests (McKellop et al., 1978; Treharne et al., 1981). In other studies the amount of wear debris retrieved from the lubricant was measured (Swanson et al., 1973; Rose et al., 1984). Neither of these methods was suitable for the present study, because localizing the wear is not possible with these methods. For this reason, the dimensional method was used (Rostoker and Galante, 1979), with the disadvantage that not only the true wear was measured, but also the cold flow of the material.

The smaller initial size of the contact area on the lateral side of the prostheses was probably responsible for the pronounced increase of the contact area after the test, the larger reduction of height on the surface profile scans and the higher surface roughness on the lateral side.

From the pressure diagrams of the Fuji pressure-sensitive films it was clear that after the tests more color intensity was present. Because there was also an increase of the contact areas, it is not logical to conclude that the higher color intensity was caused by a higher contact pressure. It is more likely that this phenomenon is caused by the increased surface roughness, which results in more contact points within the roughened, incongruent contact area. The more contact points within the surface area exceed the necessary pressure to turn the pressure-sensitive cells red, the higher the color intensity. If this theory is correct it means that a comparison of contact stresses with a pressure-sensitive film of several types of prosthesis is not reliable without prior knowledge of the roughness of the material.

The polyethylene of the PCA primary prostheses (Chapter 3) proved to be completely different from the polyethylene of the PCA modular prostheses analyzed in this study. In both prostheses, the material was crosslinked, but the crystallinity of the modular type is lower, which should lead to better wear resistance (Rose et al., 1980). There was also a different kind of surface treatment provided to the two types, because in the modular type an influence of the surface treatment was found in the heating curve of this surface with differential scanning calorimetry. In the primary PCA prosthesis the influence of

this treatment was not only limited to the surface, but also detectable in the interior of the prosthesis

Light microscopy of 7 µm thick sections showed a better moulding of the material and a thinner surface layer (50 µm instead of 200 µm) for the modular prostheses in comparison with the primary one Under this surface layer a homogeneously moulded inner portion was seen. In contrast, a badly moulded layer, followed by an inner part with a better moulding process, was seen in the primary PCA (Chapter 3).

The number of cycli chosen for the tests was based on the findings of Wright (as cited by Peterson et al 1988) that 100,000 cycli produced damage to the polyethylene, corresponding to approximately 2 years of clinical service This finding reflects the fact that in the laboratory wear occurs much faster than in vivo, because typical patients produce much more loading cycles than 100,000 per year Treharne (1981) stated that an average patient was expected to walk one million steps a year But for this study it was not necessary to perform such a large number of cycli, because a clear relation between wear and alignment could already be found with a limited number of cycli Why in joint simulators wear vivo occurs much faster than in vivo is not known

Although only 5 tests were performed, there seems to be a clear relation between the position of the loading axis and the amount of wear There is more rapid progression of wear on the lateral side than on the medial side, which must be caused by the smaller lateral contact area The generated wear increases rapidly with a more eccentric position of the loading axis (mechanical axis of the leg) This means that for all low constrained total knee replacements with small contact areas, accelerated polyethylene wear can be expected in the case of malalignment

With the introduction of the PCA modular prostheses Howmedica improved the polyethylene used by means of a different surface treatment, a lower crystallinity, and a better moulding process Unfortunately, they did not produce polyethylene inserts with a reproducible shape, and although the differences were small, a direct influence on the size of the contact areas was found

5. THE CAUSES OF MALALIGNMENT

5.1 Introduction

In Chapter 1, the goals of aligning the prosthesis were discussed. We have seen that in order to produce a mechanical leg axis through the center of the knee, the femoral angle $\alpha 3$ (Fig. 1.2.a) must equal the tibial angle β (Fig. 1.2.b). And in order to produce a transverse knee axis oriented in accordance with the PCA philosophy, both these angles should equal 87 degrees.
The PCA guiding instruments used for this purpose were also discussed in Chapter 1. They must ensure that the femoral and tibial bone cuts are made in such a way that the femoral component angle $\alpha 1$ equals 87-$\alpha 2$ degrees, and that the tibial component angle measures 87 degrees. In order to obtain the correct femoral component angle, the angle $\alpha 2$, between the femoral shaft axis and the femoral mechanical axis, must be measured on pre-operative, full-femur radiograms, and the correct femoral cutting jig for 7, 9 or 11 degrees must be applied.
In Chapter 2 it was shown that malalignment occurred in over 50% of the clinical cases investigated. In this Chapter an attempt is made to discover, retrospectively, why the prostheses were malaligned. For this purpose, pre- and per-operative data of the patient group was studied, and the post-operative radiograms were measured. The questions addressed were whether the pre-operative procedure was followed correctly, whether the correct femoral cutting jig was chosen, whether the guiding instruments were accurate enough and whether they were correctly used.

5.2 Material and methods

The patient series was presented in Chapter 2. From the total of 121 PCA prostheses, 119 were studied here. Two cases had to be excluded, one because of subsidence of the tibial component and the other because of a revision to another type of prosthesis.
The roentgen files of the patients were investigated to see if full-femur pre-operative radiograms had been made for the assessment of the angle $\alpha 2$ and the determination of the correct femoral cutting jig. The per-operative reports were studied to find out which femoral cutting jig (for 7, 9 or 11 degrees) had actually been applied. If there was no mention of the jig angle in the report, it was assumed that the 9 degrees jig had been used, because that is the normal standard, according to the manufacturer.
Full leg-length weight bearing post-operative radiograms including the femoral head and the ankle joint were used for the radiological assessment (Fig. 5.1). On the femur, the femoral shaft axis, the transverse femoral axis and the femoral mechanical axis were drawn and the angles $\alpha 1$ and $\alpha 2$ (Fig. 1.2.a) were measured. The correct femoral component angle $\alpha 1$ could be calculated as 87 - $\alpha 2$ degrees. The difference between the measured and the calculated femoral component angle was recorded as negative (relative varus

Figure 5.1: Full-leg length weight-bearing radiogram

orientation) when the measured angle was bigger than the calculated one and positive (relative valgus orientation) for the opposite (see Fig. 5.2.a). Deviations between the measured and the calculated femoral component angle must be due either to a wrong choice of the cutting jig, an inaccurate femoral guiding instrument or an incorrect use of this instrument.

On the tibial side, the tibial mechanical axis and the transverse tibial axis were drawn and the medial angle between these two was measured (angle β in Fig. 1.2.b). This angle should ideally be 87 degrees. The difference between the measured and the perfect angle was recorded as negative (relative varus orientation) when the measured angle was less than 87 degrees and positive (relative valgus orientation) when it was more than 87 degrees (see Fig. 5.2.b).

For the whole leg, the mechanical axis and the transverse knee axis were drawn. On the transverse axis the center of the prosthesis was located and the distance between the center of the prosthesis and the mechanical axis measured; negative for a location in the medial compartment (varus position) and positive for a location in the lateral compartment (valgus position), as illustrated in Fig. 5.2.c. The angle between the femoral shaft axis and the mechanical tibial axis was also measured. This angle ($\gamma 1$ in fig. 1.2.c) is known in the literature as the *radiological* tibio-femoral angle.

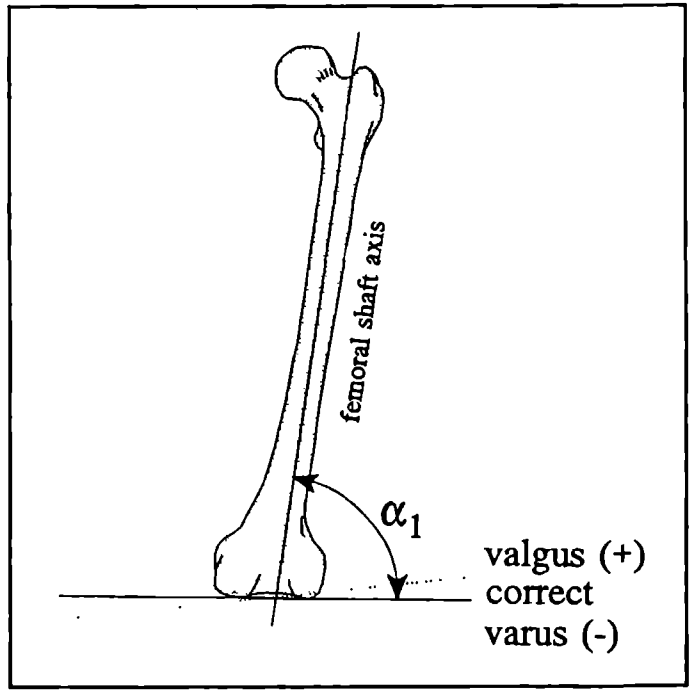


Figure 5.2a:
Drawing showing the relative varus(-) or valgus(+) position of the femoral component

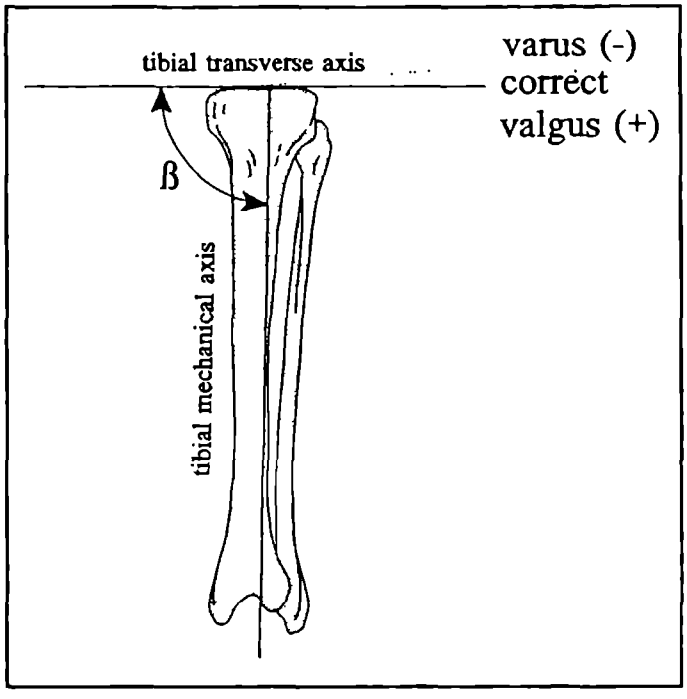


Figure 5.2b:
Drawing showing the relative varus(-) or valgus(+) position of the tibial component

Finally, for reasons discussed below, the *clinical* tibio-femoral angle was measured on the patients during the clinical investigation. This was done with a goniometer, using the center of the knee and the ankle as references for the mechanical tibial axis, and the knee center and the anterior superior iliac spine as references for the femoral shaft axis. The difference between the clinical and the radiological tibio-femoral angle was recorded. The reason for recording the difference between the clinical and the radiological tibio-femoral angle was the following. During the operation, the surgeon inserts the intramedullary rod of the femoral guiding instrument in the femoral canal (Fig. 5.3). This rod is relatively thin, and the canal relatively wide. In order to insert the rod in the correct orientation, the alignment of the leg on the operation table will be considered during the insertion. It is hypothesized, that when the anatomy of the leg is 'misleading', the surgeon will be fooled by its appearance and inserts the rod in the wrong direction. Whether the anatomy of the leg is misleading can be tested by comparing the clinical tibio- femoral angle to the radiological one. The hypothesis can then be tested by correlating the deviation between the two to the degree of malalignment.
All the above measurements are subject to measurement errors. These are caused by possible rotations of the leg relative to the roentgen cassettes, by marking errors in the

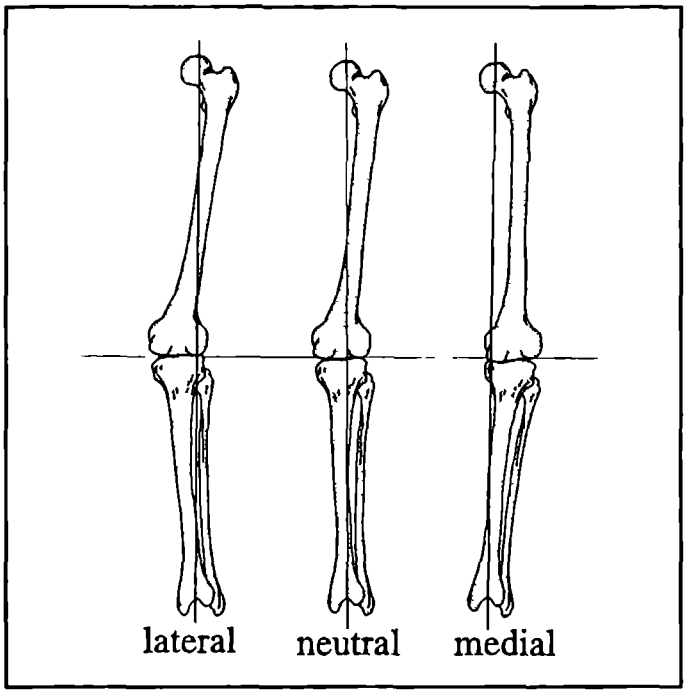


Figure 5.2c:
Drawing of a lateral, neutral and medial position of the mechanical axis

radiograms, when drawing the axes, and by reading errors from the goniometer No attempt was made to quantify these errors They were treated as being of stochastic origin in the statistical analysis

5.3 Results

5.3.1 Pre-operative procedure and selection of femoral cutting jig

Of the 119 cases studied, full-femur pre-operative radiograms were found in the roentgen files only eleven times Hence, in 108 cases these radiograms had not been available, consequently the angle $\alpha 2$ could not have been measured pre-operatively and a selection of the correct femoral cutting jig could not have been made In those eleven cases where this radiogram was available, it led to the selection of the 9 degrees cutting jig in eight cases, to the 7 degrees jig in two cases and to the eleven degrees jig in one case Whether the measurements were actually done in all cases is not known, because there were no markings on the radiograms In the eight cases the 9 degrees jig was applied, it was not correct in three cases The 7 degrees jig was applied 21 times, not because of a radiograp-

hic measurement, but because the contralateral knee had not much of a valgus appearance.
The post-operative measurement of the angle α2 revealed that the correct cutting jig had been selected in 79 cases. Hence, as discussed above, in 71 of these this occurred purely by accident. In 40 of the cases the correct jig had not been selected.

5.3.2 Placement of the femoral component

For the analysis of the femoral component angle, the series was divided in two groups,

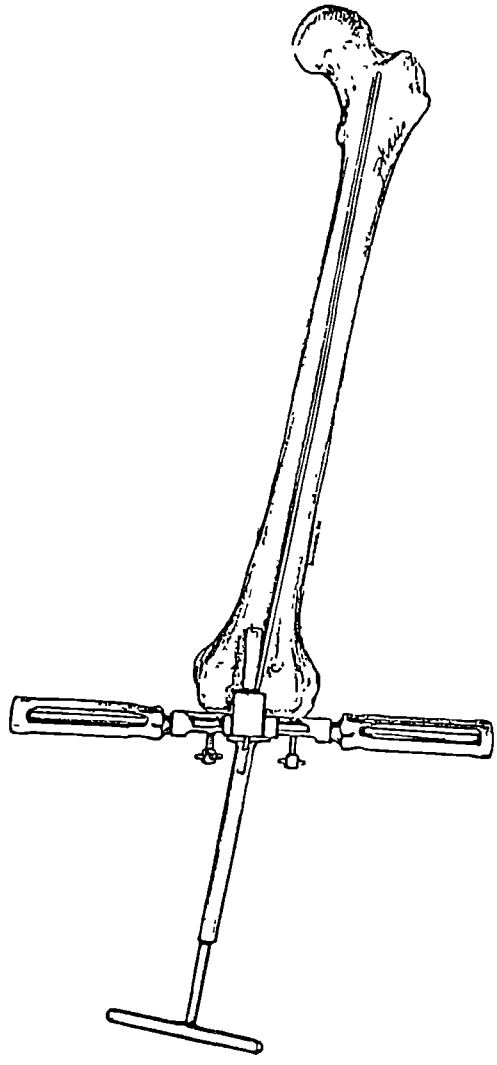


figure 5.3:
Drawing of the intra-medullary aiming/cutting jig inserted in the femur

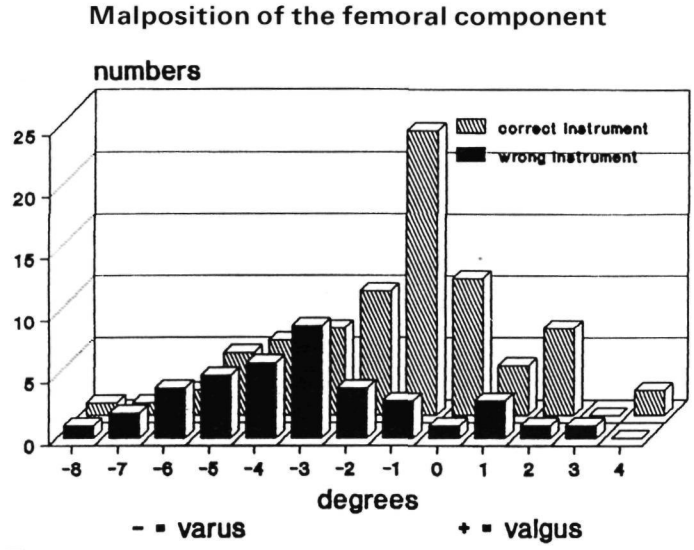


Figure 5.4:
Malposition of the femoral component in degrees for the correct and wrong instrument

one in which the correct cutting jig was used (n = 79) and one in which the correct cutting jig was not used (n = 40). The results are shown in Fig. 5.4. In most cases there is a relative varus position of the femoral component for both the correct and the wrong

Malposition of the femoral component in degrees

	correct instrument	wrong instrument
	n = 79	n = 40
average	- 1.44	- 3.12
variance	5.53	6.47
std. deviation	2.35	2.54

$p < 0.001$

Table 5.1:
Malposition of the femoral component in degrees for the correct and wrong instrument

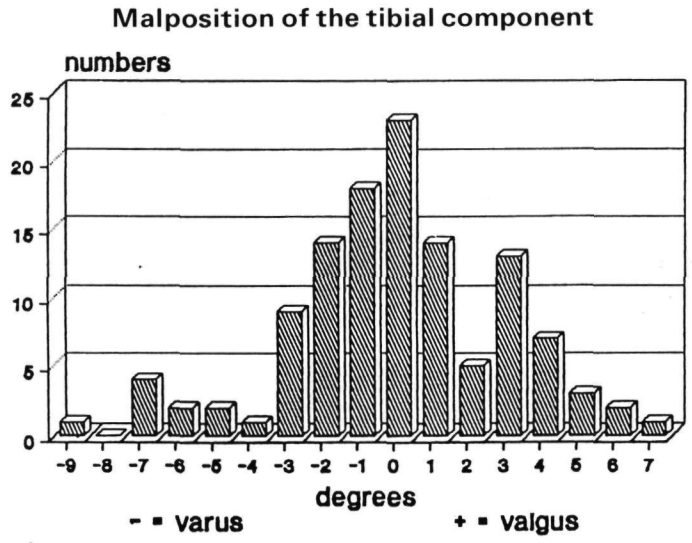


Figure 5.5:
Malposition of the tibial component in degrees

instrument groups. Statistical analysis (Table 5.1) shows a significantly better position (Mann-Whitney test) for the group in which the correct instrument had been used. Although this seems logical, it also means that the intramedullary aiming/cutting jig is

Malposition of the tibial component
in degrees

	good position femur	rel. varus femur ≥3
	n = 67	n = 49
average	-0.46	0.16
variance	9.25	8.01
std. deviation	3.04	2.83

no significance

Table 5.2:
Malposition of the tibial component in degrees for a good femoral component position and a relative varus femoral component position

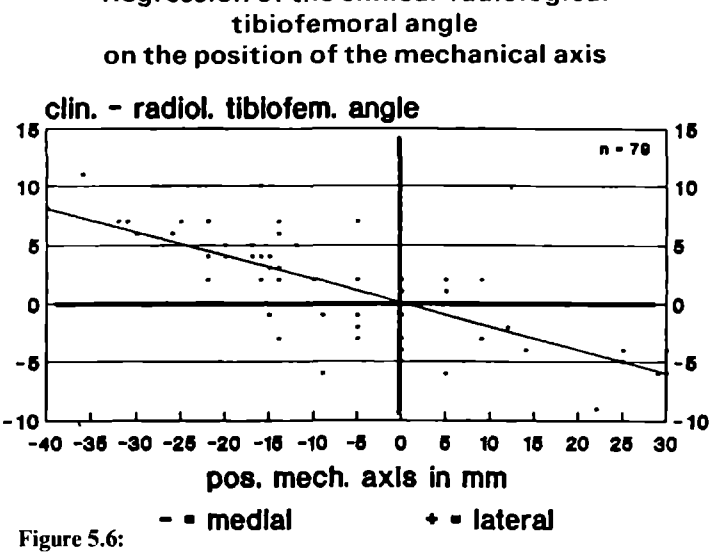


Figure 5.6:
Linear regression analysis of the clinical minus the radiological tibiofemoral angle on the position of the mechanical axis

precise enough to distinguish a difference of 2 degrees, which was the average difference between the right and the wrong cutting-jig angles On the other hand, the system allowed an average varus position of 1 4 degrees when the right jig was used, which is either caused by an incorrect use of the instrument or by the instrument itself

5.3.3 Placement of the tibial component

The position of the tibial component was evaluated and again the differences between the ideal and the measured position was recorded and is shown in Figure 5 5 The correct position was achieved in 18,2% of cases An acceptable range, of one degree relative varus to one degree relative valgus, was seen in 44,6% of cases Two or more degrees relative varus (26,4%) or valgus (29%) positions were devided almost equally This result is certainly not perfect, but because the tibial cut was made after the femoral one, it is possible that an error in the latter had an adverse influence on the former To find out whether this was the case, the position of the tibial component was studied for a group with a good position of the femoral component (2 degrees varus or valgus, or less) in comparison with a group with a relative varus position of the femoral component 3 degrees or more Statistical analysis (Table 5 2) showed no significant difference between these groups (Mann-Whitney test) This means that the tibial cut was made independently from the femoral cut From the variances and the high standard deviations, the conclusion can be drawn that the tibial aiming/cutting jig is not a very precise instrument

5.3.4 The effect of a misleading leg shape

To test the hypothesis, presented above, that a misleading leg shape has an adverse effect

Malposition of the femoral component in degrees

	clin-rad T.F.A.≤+/-3	clin-rad T.F.A. >3
	n = 42	n = 23
average	- 0.85	- 3.17
variance	4.32	4.33
std. deviation	2.07	2.08

$p < 0.001$

Table 5.3:
Malposition of the femoral component in degrees without and with a misleading leg shape

on alignment, the difference between the clinical and the radiological tibio-femoral angle was correlated with the degree of malalignment of the mechanical axis of the leg. Only the group of cases in which the correct femoral cutting jig had been applied was conside-

Malposition of the tibial component in degrees

	clin-rad T.F.A.≤+/-3	clin-rad T.F.A. >3
	n = 42	n = 23
average	0	- 1.86
variance	6.39	7.48
std. deviation	2.52	2.73

$p < 0.01$

Table 5.4:
Malposition of the tibial component in degrees without and with a misleading-leg shape

red in this analysis. A regression analysis of the clinical minus the radiological tibio-femoral angle with the position of the mechanical axis is shown in Fig. 5.6 (R-squared = 56%, correlation coefficient = -0.75, standard error of estimation - 2.58). This figure shows that when there was a medial position of the mechanical axis (relative varus) the clinical tibio-femoral axis was bigger than the radiological one (the upper left quadrant), meaning that the outer shape of the leg suggested more valgus than there in fact was. The lower-right quadrant (Fig. 5.6) represents a lateral position of the mechanical axis (relative valgus) and a clinical tibio-femoral angle smaller than the radiological one, meaning that the outer shape of the leg suggested less valgus than there actually was. From this it can be concluded that the shape of the leg has an influence on the alignment. This however is only possible if one or both aiming/cutting jigs are not used in a correct way. To study this phenomenon the position of the femoral component was analyzed in a group of patients without a misleading leg shape (clinical minus radiological tibio-femoral angle less than ± 3 degrees) and compared with a group with a misleading leg shape (clinical minus radiological tibio-femoral angle, equal or more than 3 degrees). The results showed (Table 5.3) a significantly better position when the leg shape was not misleading. Looking at the average it is clear that the instrument is not used correctly especially for the group with the bigger clinical tibio-femoral angle. It is important to note that the average malposition of the femoral component was reduced to only -0.85 degrees when there was hardly any difference between the two tibio-femoral angles. For the tibial component the same pattern was found, but here the significant level was (Mann-Whitney test) 0.01 instead of 0.001 (Table 5.4).

5.4 Discussion

The surgical technique of the PCA prosthesis prescribes that an A/P radiogram of the femur is necessary to determine the appropriate angle of the cutting jig. It is mentioned also that 9 degrees is the average (Kenna et al., 1984). This is probably the reason why this angle of the instrument was used routinely.
In the literature it has been stated that achieving a good alignment was difficult, but a thorough investigation of the aiming/cutting instruments is not found. From this study it can be concluded that the extra-medullary tibial jig is not a precise instrument in comparison with the intra-medullary femoral one, but it can not be compared with extra- or intramedullary tibial jigs of other prostheses.
The conclusion for the femoral jig is that it is a rather precise instrument, which is not always properly used. Possible reasons could be that the rather thin intra-medullary rod is not placed in the middle of the medullary canal. This can happen when the surgeon projects the femur in an other direction than that it actually runs (misleading leg shape). This mistake can be made more easily in the osteoporotic bone (wider medullary canal) and when the intra-medullary rod is not introduced far enough into the medullary canal (Fig. 5.7).
It seems logical to conclude that the instruments have to be improved and that anatomic

landmark demarcation instruments (Ritter and Campbell, 1988) may be helpful particularly in cases with a misleading leg shape. But of much more importance is that the orthopaedic surgeon must perform the operation only after a complete pre-operative planning. This includes measuring the clinical and the radiological tibio-femoral angles, necessary to detect a misleading leg shape, and the $\alpha 2$ angle, to be able to chose the correct cutting jig. Proper investigation and critical evaluation of ones own results, of course, will produce feed-back learning and eventually better alignment.

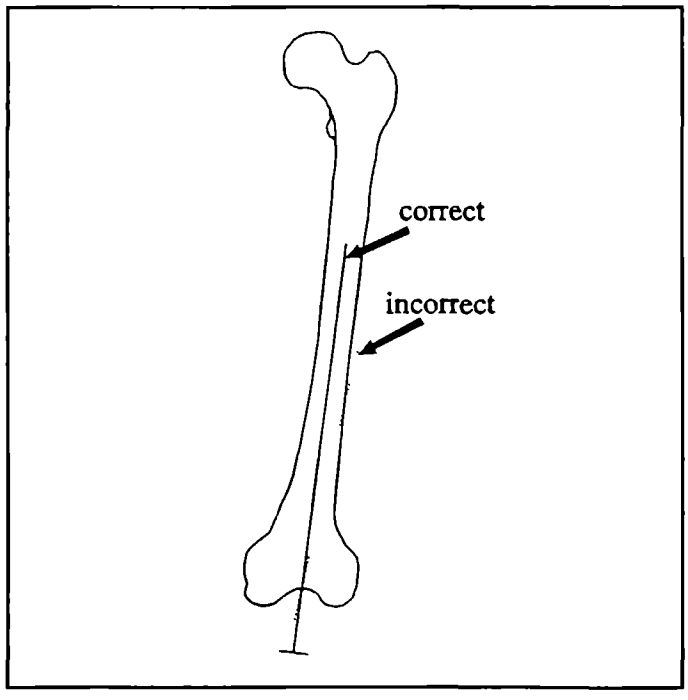


Figure 5.7:
Drawing of the intra medullary rod inserted in the femur in a correct and incorrect position

6. DISCUSSION AND CONCLUSION

Success or failure of a Total Knee Replacement depends on patient, surgical and prosthetic factors. Following the success of Total Hip Replacement, TKR has developed to a sophisticated and widely accepted treatment for the severely destructed knee. Although the first constrained and semi-constrained hinge-like prostheses presented severe functional limitations, early component failures and loosenings, the modern unconstrained total-condylar type knee prostheses have shown to allow performance and endurance similar to those after hip arthroplasty (Ranawat and Boachie-Adjei, 1988). As a result, TKR has become more popular, is increasingly preferred over other treatment modalities, such as tibial osteotomy, and an increasing number of orthopaedic surgeons became involved in its application. In the USA, knees are replaced now almost as frequently as hips. In addition, knee prostheses have become big business for the orthopaedic companies, bringing profit in similar numbers as hip prostheses. In order to keep or boast their market shares, they must generate 'innovations' and 'improvements' continuously, in prosthetic designs, materials or surgical instruments.

The clinical study presented in Chapter 2 clearly showed that the post-operative results were better in terms of the HSS scores when the pre-operative scores were higher. The explanation of this phenomenon is not difficult to imagine. The total-condylar type prostheses are so-called 'anatomic' reconstructions in which both the anatomy and the kinematics of the normal joint are closely imitated, whereby the soft tissues also play an important role. Since the pre-operative HSS scores represent the advance of the underlying disease, a low score usually represents advanced destruction of the normal anatomy, for which a successful reconstruction is less likely. This brings us to a contradiction. On the one hand it must be recognized that no joint replacement endures forever, hence the shorter the life expectancy of the patient, the less the probability that one or more revisions (however with an acceptable result according to Goldberg et al., 1988; Jacobs et al., 1988; Samuelson 1988 and Windsor et al., 1986). are required during his lifetime. From this prospective, it is advantageous to wait as long as possible. On the other hand, however, the prospects for a successful reconstruction are better when the patient is referred for surgery early in the development of the disease. What the optimal moment is, depends very much on the characteristics of the patient, such as age, activity level, general health condition and advance of the disease. But certainly a proper selection of the right moment also requires knowledge and experience with respect to knee-replacement surgery, which general practitioners usually do not possess. In fact, general practitioners in the Netherlands often seem to have an outdated, negative picture about the prospects of total knee replacement. A better education of the general practitioners in this sense, or direct referral of the patients to the orthopaedic surgeon, are the only ways to avoid useless suffering and inferior initial conditions for a necessary knee replacement.

In the introduction (Chapter 1) the questions were posed whether the innovative products that reach the market are really improvements above the traditional, well-tried 'golden standard' of the Total Condylar Knee prosthesis (Ranawat and Boachie-Adjei,

1988), whether they are safe and whether they are properly tested. It was also questioned whether the surgical instruments accomplish what they are intended for; whether the instructions are clear enough for the typical orthopaedic surgeon who does not consider himself to be a TKR sub-specialist, and if such a surgeon is properly trained and experienced to perform such a theoretically and practically complex operation.
It was shown here once again that these questions can not be answered by a traditional retrospective clinical follow-up study on the mid-long term, even if multiple centers are involved. Our clinical multi-center follow-up study merely gave some indications towards the answers to the above questions, whereby it was near to impossible to differentiate between patient, surgical and prosthetic effects on the post-operative results. The overall clinical results could be designated as 'adequate', but only barely so, relative to other results reported in the literature. Of course, other retrospective follow-up studies suffer the same limitations, i.e. small series, too many surgical and prosthetic variables, short follow-up periods, subjectiveness in the scoring system and biases. There were indications, however, that much wear had occurred during the relatively short follow-up period studied, and that the series had been subject to a 'learning curve'. That is to say, the clinical results seemed to improve depending on the experience of the surgeons with the particular prosthesis concerned. A definite and disturbing finding was that the prosthesis had been seriously malaligned in over 50% of the patients.
Malalignment has a definite effect on wear rates, as was shown here in Chapter 4. Hence, it should be avoided, although this is easier said than done. Proper alignment has three aspects. First of all is the matter of the philosophy, i.e. setting the goals for alignment, which is the prerogative of the designer (or 'author') of the particular prosthesis. It is generally accepted that the mechanical leg axis (line center hip to center ankle in the frontal plane) should cross the center of the knee, in order to distribute the knee-joint load evenly over the medial and lateral compartments. This consensus is based, however, first of all on the assumption that the higher knee-joint forces during variable knee-joint functions (e.g. walking, stair ascending and descending, etc.) are directed along the mechanical axis. Although this is certainly true for the static, relaxed double-legged stance (Rozing, 1976), it is certainly not true for many dynamic functions (Andriacchi and Mikosz, 1991). A better argument for central alignment of the mechanical axis is probably that it accords with the anatomic configuration of the normal leg. The second assumption underlying the requirement for central alignment is that equal load sharing is desirable. This assumption is all but trivial. In fact, there are many indications that in the normal knee the medial compartment is more highly loaded than the lateral one (Andriacchi and Mikosz, 1991). In many knee prostheses the medial contact area is larger than the lateral one in order to mimic the normal knee geometry and kinematics, and this is also the case for the PCA, as shown in Chapter 4. Hence, central component loading means equal load sharing, but the smaller lateral contact area is bound to cause higher contact pressures and higher wear rate on that side, which was actually established in Chapter 4. In other words, if the prosthesis is designed in such a way that the medial contact area is the largest, it may be advisable to ensure a larger share of the load on that side. In addition to a central position of the mechanical axis, the designers of the PCA

require a prosthetic component angle of 87 degrees to achieve a horizontal position of the components during the one-legged stance phase in gait. Whether this is the optimal configuration for load transfer in variable functions is again questionable, but difficult to establish based on the knowledge presently available. The guideline is also based on the assumption that all patients have identical kinematic gait patterns, in the sense that the angle between the mechanical axis and the vertical is 3 degrees during the one-legged stance in gait. This is certainly not true, and maybe the component angle should be a variable one, depending on the characteristics of the patient. These arguments, however, only illustrate that the goals for proper alignment of a prosthesis are subject to debate. It is not our intention to suggest that the individual, peripheral orthopaedic surgeon should experiment with alternative alignment. In fact, the philosophy of proper alignment is an integral part of a prosthetic design, and the responsibility of the designer. If a surgeon does not accept the philosophy, he should not use the prosthesis concerned. If he does use it, he should abide by its implantation guidelines. In order to accomplish that, he should be aware of the philosophy, of course.

The second aspect of proper alignment is the efficacy of the surgical instruments in reaching the alignment goals, which brings us back to the question whether these can accomplish what they were intended for. The third aspect concerns the actual use of the instruments during surgery and is related to the question whether the surgeon has adequate training and experience, and whether the instructions from the company are adequately clear. These aspects are very difficult to separate, for the obvious reason that it remains a matter of debate whether the teacher or the student is at fault when the student errs.

However, there were indications in the statistics presented in Chapter 5 that the intramedullary femoral guiding instrument is a precise one, in the sense that it produces good results if used correctly, i.e. is inserted in the center of the canal. The tibial, extra-medullary aiming jig, however, was found to be less precise, even if used according to the guidelines. Hence, a better method should be found to determine the orientation of the tibial bone cut. Where the instructions for the use of the instruments are concerned, these are elaborated in the monograph of Kenna et al. (1984).

Hence, the conclusion is obvious that the 50% malalignment found in the clinical results is largely a matter of surgical errors, and this was confirmed in Chapter 5. first of all, it became evident that the femoral aiming instrument had not been used correctly if the outer shape of the leg was misleading. In other words, the surgeon often let himself be guided by the visual appearance of the outer leg anatomy at the operating table, rather than navigate based on pre-operative planning and designer guidelines for the instruments; hence, an ad hoc approach is often preferred. Secondly, it was found that pre-operative full-leg radiograms were hardly ever made and if at all, they were hardly ever measured. These radiograms are indispensable for pre-operative planning and required in particular to determine the type of femoral cutting jig to be used during the operation. Why these pre-planning procedures were not performed can only be guessed at, but it is a serious mistake, for which the designer nor the company are responsible. Based on these findings, one may question whether complicated operations such as total knee

replacement, for which both experience and theoretical know-how are indispensable, should not be concentrated in a limited number of hospital centers, as a sub-specialty of orthopaedics

Where the design of a prosthesis is concerned, the surgeon is responsible only for selecting brand, type and size. The design itself, the quality of its materials and manufacturing processes are the responsibility of the company and the designer (or 'author') Prosthetic 'authors' are usually bioengineers and orthopaedic surgeons, who develop concepts for the kinematic characteristics of the prosthesis, its constraints and freedom of motion, contact area type and bone fixation mode The manufacturing companies must ensure that this concept is realized in a safe and effective device To select a particular type of prosthesis, the surgeon must accept the philosophy behind its design, just as for the instrumentation Hence, this philosophy should be documented in such a way that its merits can be assessed by a surgeon Where the quality of the materials and the manufacturing process are concerned, the surgeon can but navigate on trust or the efficacy of Government-regulation procedures, if available in his country (Faro, 1990)

The analyses of the PCA primary prosthesis, described in Chapter 3, clearly showed that its tibial plateau, although probably made out of good quality polyethylene, was of inferior strength and flexibility, due to the manufacturing process, which included a surface heat treatment. Although the motive for this additional treatment - the creation of a smooth surface - was certainly a positive one, its detrimental effects on the material structure and the early failures it would generate were not anticipated The manufacturing process was later improved for the PCA modular prosthesis, as shown in Chapter 4, and the contact area shape was changed as well However, it was also found that the surface dimensions were not reproducible, which has a profound effect on the actual contact area, hence also on contact pressures and wear. This problem may be inherent to the molding process of UHMWPE, hence unavoidable, but it should be studied further. It is evident that particularly for the unconstrained total condylar type knee prostheses, with their relatively small contact areas, the quality of the polyethylene is critical, and companies as well as surgeons should be aware of that. The fault in this case, relative to the PCA, does not entirely lie with the company The USA has an extremely strict Government-regulation system for market approval of medical devices, administered by the Food and Drug Administration (FDA) (Faro, 1990) Approval of implants must be based on evidence of efficacy and safety in pre-clinical and clinical tests, which are checked by the Center for Devices and Radiological Health (CDRH) The PCA primary prosthesis had been approved for sales in the open market, as published in the Federal Register (1988) CDRH documented its approval in Dockets Management branch docket no 88M-0364 Laboratory testing had shown that the polyethylene fulfilled the conditions of the standard specification for 'Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants' (ASTM designation F648-84) In addition, clinical trials had been performed and the results were evaluated after two years post-operatively No post-operative (retrieval) evaluation had been required Nevertheless, the PCA primary prosthesis has not proven itself as a safe device The conclusion is inescapable, that the US Government regulation procedure - which does not exist

in the Netherlands (Faro, 1990) - has been followed correctly, but that the standards used for clinical and pre-clinical testing were inadequate. This is sad, the more so if one realizes that extensive pre-clinical testing in knee simulators - such as described in Chapter 4 - would probably have revealed the deficiencies in the PCA.

Before we draw the two most important conclusions from the work described here, one should appreciate that Total Knee Replacement has developed, generally speaking, to a highly effective and successful treatment for the severely disabled, parallelling that of hip replacement. This success has been reached at the cost of many early failures and years of sophisticated clinical and experimental research in patho-physiology, biomechanics, biomaterials and production technology However, individual success is not a bread-and-butter accomplishment guaranteed forever. It takes know-how, training and experience, precise indications and well-tested prostheses and instruments, for which the companies and the surgeons, together, are responsible.

It must be concluded, firstly, that orthopaedic companies should involve themselves, voluntarily, in more rigorous pre-clinical and clinical testing procedures, because it is unrealistic to assume that the development of standards, used in Government regulation procedures, can keep up with the rate by which materials and design innovations appear on the market

Secondly, it must be concluded that Total Knee Replacement requires, as a sine-quanon, full-leg load-bearing radiograms pre-operatively and post-operatively, at a reasonable frequency for as long as the patient has the prosthesis This is a necessity, respectively, to pre-plan the operation, to check ones own surgical technique and, if necessary, improve it and, on the longer term, to check for the development of wear, in order to be able to take timely measures when it becomes excessive. Each time, the position of the mechanical leg axis must be reconstructed and measured relative to the prosthesis Without this, TKR is a half measure only, whatever the quality of the design or the surgeon.

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8. SUMMARY

In chapter 1 a survey for the treatment of the arthritic knee joint is given. The total knee replacement has become more important over the years, specially the low constrained total condylar type prostheses. One of the specific problems of these prostheses, is polyethylene wear caused by high contact stresses in the material. The safety of the prostheses and the accuracy of the instrumentation set is discussed. Furthermore the problem polyethylene wear and alignment is defined. Besides a historical survey of the total knee replacement is given in this chapter, as well as a description of the Porous Coated Anatomic (PCA) knee, the alignment problem is assessed for total knee replacement in general and for the PCA prosthesis in particular. Also the setup of this thesis is described.
In chapter 2 the clinical results of 107 patients with 121 PCA total knee prostheses treated in 7 dutch clinics are described in a retrospective study. The results are compared with those from the literature. The relation between clinical result and age , body-weight, length of implantation, cemented or uncemented implantation and alignment were studied.
From radiological assessment, it was clear that malalignment occured in over 50% of the cases, and besides there was a suspicion of polyethylene wear in 9%.
In chapter 3 the different forms of polyethylene wear are described as well as the factors that influence this wear. The polyethylene of 2 retrieval cases with accelerated wear after 3 years was analysed. The molecular weight was measured, the morphology studied by light microscopy and the crystallinity calculated with differential scanning calorimetry. The quality of the polyethylene proved to be negatively influenced by heat pressing of the surface. The importance of full-leg length, weight-bearing radiographs at follow-up is stressed because they can reveal polyethylene wear in an early stage. This is important because in this early stage the treatment of wear can be limited to a synovectomy and a replacement of the polyethylene insert for the modular type prosthesis.
In chapter 4 the relation between polyethylene wear and alignment was studied in a laboratory. The PCA knee prosthesis was placed in a knee joint simulator with a central and progressively eccentric loading. The wear was measured with the dimensional method and the surface roughness was measured as well and the contact area recorded with a pressure sensitive film. The surface of 1 prosthesis was studied by light and scanning electron microscopy. On an other prosthesis the morphology and crystallinity as described in chapter 3 was analysed. From the results a clear relation could be found between the amount of wear and the position of the mechanical axis. The wear increased rapidly with a more eccentric loading. At the lateral side there was more wear recorded than in the medial compartment. A possible explanation can be the smaller contact area found at the lateral side. From the material analysis it was clear that the polyethylene of the PCA modular prosthesis (used in the tests) had been improved in comparison with the polyethylene of the PCA primary prosthesis.
In chapter 5 the malalignment as described in chapter 2 is assessed by means of pre- and per-operative data. On full-leg length, weight-bearing radiographs the position of the

femoral and tibial component were measured separately as well as the radiological tibio-femoral angle, which was compared with the clinical tibio-femoral angle Inaccurate pre-operative planning proved for several cases to be the cause of an incorrect femoral cutting jig used at the operation However this intra-medullary jig showed to be a rather precise instrument which is not always properly used This happened when there was a misleading shape of the leg (a marked difference between the clinical and radiological tibio-femoral angle) From the position of the tibial component could be concluded that the tibial cutting jig is not a very precise instrument because a large standard deviation was seen

In chapter 6 the results of the separate chapters are discussed in relation to what was stated in the introduction Special attention is given to the alignment problem and its effect on the different contact areas of the prostheses and indirectly on the amount of polyethylene wear. Furthermore the safety of the prosthesis in relation to the approval administered by the Food and Drug Administration is discussed This is interesting because the FDA approval did not guarantee the safety of the studied implant From this it can be concluded that extended pre-clinical and clinical testing should be performed voluntarily by the companies who market these prostheses Again the importance of full-leg length, weight-bearing radiographs pre- and post-operative is stated.

9. SAMENVATTING

In hoofdstuk 1 wordt een algemeen overzicht gegeven van de behandeling van de arthrotische knie De knieprothese speelt hierbij een steeds grotere rol, in het bijzonder de low constrained total condylar type prothesen Het specifieke probleem van deze prothesen, is polyethyleenslijtage tengevolge van hoge druk op dit materiaal Ook wordt de veiligheid van prothesen en de doelmatigheid van het inbreng-instrumentarium naar voren gebracht Aan de hand hiervan wordt de probleemstelling (polyethyleenslijtage en plaatsing van de prothese) en opzet van deze studie beschreven Bovendien wordt er in dit hoofdstuk een historisch overzicht gegeven van de knieprothese, een beschrijving van de Porous Coated Anatomic (PCA) knie, en wordt het alignement probleem beschreven voor knieprothesen in het algemeen en voor de PCA prothese in het bijzonder
In hoofdstuk 2 wordt in een retrospectieve studie het klinische resultaat beschreven van 107 patienten met 121 PCA knieprothesen die behandeld werden in 7 verschillende klinieken Dit resultaat wordt vergeleken met gegevens uit de literatuur Ook wordt er gekeken of er relaties zijn tussen het klinische resultaat en leeftijd, lichaamsgewicht, lengte van implantatie, het al dan niet gecementeerd zijn van de prothese en het alignement Bij radiologische evaluatie blijkt het alignement in 50% van de gevallen onvoldoende en is er bovendien een verdenking op polyethyleenslijtage bij 9%
In hoofdstuk 3 worden de vormen van polyethyleenslijtage beschreven evenals de factoren die invloed hebben op deze slijtage Het polyethyleen van 2 patienten waarbij een revisie werd verricht wegens volledige slijtage van het tibiaplateau na 3 jaar, werd geanalyseerd Hierbij werd het molecuulgewicht gemeten, de structuur bestudeerd met lichtmicroscopie en de kristalliniteit berekend met gedifferentieerde scanning calorometrie Hieruit bleek de kwaliteit van het polyethyleen negatief te zijn beinvloed door een oppervlaktebehandeling van het materiaal Verder wordt het belang van lange staande beenopnamen bij de follow-up van knieprothesen benadrukt omdat op deze rontgenfoto's polyethyleenslijtage in een vroeg stadium kan worden gediagnostiseerd, waardoor bij moderne modulaire knieprothesen de behandeling van deze slijtage beperkt kan blijven tot een synovectomie en tot vervanging van het polyethyleen deel
In hoofdstuk 4 wordt een laboratoriumstudie beschreven waarin, door plaatsing van een PCA knieprothese met verschillende ligging van de mechanische belastingsas in een kniesimulator, de relatie tussen alignement en polyethyleenslijtage bestudeerd wordt De polyethyleenslijtage wordt vastgelegd volgens het oppervlaktemodel waarbij het oppervlak van voor naar achter en van perifeer naar centraal wordt opgemeten Verder wordt de oppervlakteruwheid gemeten, het contactvlak vastgelegd op een drukgevoelige film Het oppervlak van 1 prothese werd met licht- en scanning electronenmicroscoop onderzocht Zoals beschreven in hoofdstuk 3 werd ook het materiaal geanalyseerd Uit de resultaten blijkt een duidelijke relatie tussen de positie van de mechanische belastings-as en de mate van slijtage Deze slijtage neemt snel toe bij een meer a-centrale ligging van deze as De toename is aan de laterale zijde sterker dan aan de mediale zijde Een verklaring hiervoor is waarschijnlijk het kleinere contactvlak aan de laterale zijde Uit de materiaalanalyse

blijkt het polyethyleen van de bij deze testen gebruikte PCA modular prothese duidelijk verbeterd te zijn ten opzichte van het polyethyleen van de PCA primary prothese
In hoofdstuk 6 wordt het probleem van het slechte alignement zoals beschreven in hoofdstuk 2 nader onderzocht Hiervoor worden pre- en per-operatieve gegevens bestudeerd. Op staande rontgenfoto's van het gehele been worden de posities van de afzonderlijke componenten gemeten evenals de radiologische tibiofemorale hoek die vergeleken wordt met de klinische tibiofemorale hoek. In eerste instantie blijkt dat tengevolge van onvoldoende pre-operatieve planning niet altijd het goede femorale richtinstrument gebruikt wordt, hoewel dit een redelijk nauwkeurig instrument blijkt te zijn De toepassing ervan is niet altijd juist, met name als er een duidelijk verschil is tussen de klinische en radiologische tibiofemorale hoek (met andere woorden een misleidende vorm van het been) Uit de plaatsing van het tibiaplateau blijkt dat het tibiale richtinstrument een zeer grote spreiding toelaat en dus niet erg nauwkeurig genoemd kan worden
In hoofdstuk 6 worden de resultaten van de afzonderlijke hoofdstukken besproken en in een breder kader geplaatst zoals dit was omschreven in de inleiding, waarbij de aandacht vooral gericht is op het probleem alignement en het effect hiervan op de verschillende contactvlakken van de prothese en daarmee op de slijtage van het polyethyleen Ook wordt de veiligheid van de prothese verder besproken aan de hand van de goedkeuringsrapporten van de Amerikaanse Food and Drug Administration, die niet waterdicht blijken te zijn. Hieruit blijkt de noodzaak dat pre-klinische en klinische testprogramma's moeten worden uitgebreid door de firma's die deze prothesen op de markt brengen Verder wordt er nog op het belang van lange staande rontgenopnamen van het gehele been gewezen zowel pre- als post-operatief

10. CURRICULUM VITAE

Niek Tulp werd op 27 april 1954 geboren te Zwolle. Na zijn middelbare school (H.B.S.-b) studeerde hij geneeskunde aan de Rijks Universiteit Groningen, waar hij in 1980 het arts-examen haalde.
Van 1980 tot 1981 werkte hij als A.G.N.I.O. op de afd. orthopaedie van het Lucas Ziekenhuis te Amsterdam onder verantwoording van Dr. R. van Dijk en P.G. Vermes.
Van 1981 tot 1982 werd de militaire dienstplicht vervuld bij de Koninklijke Luchtmacht te Soesterberg.
Van 1982 tot 1983 werkte hij als assistent orthopaedie in het St. Elisabeth Hospitaal te Willemstad Curaao.
Na terugkomst in Nederland startte hij zijn chirurgische vooropleiding in het Diaconessen Ziekenhuis te Heemstede met als opleider Dr. H.W.R. Siebbeles. Aansluitend werd in het Slotervaart Ziekenhuis te Amsterdam, onder leiding van Dr. K.J. Hamelynck, gedurende een jaar opleiding genoten in de orthopaedie.
Van begin 1987 tot eind 1990 werkte hij in het De Wever Ziekenhuis te Heerlen, waar met Dr A.J. Tonino als opleider, de orthopaedische vorming werd voortgezet.
Op 1 januari 1991 vond inschrijving als orthopaedisch chirurg in het specialistenregister plaats. Vanaf deze datum werkte hij als Chef de Clinique in het Ziekenhuis De Weezenlanden te Zwolle, waar hij per 1 januari 1992 werd opgenomen in de orthopaedische maatschap samen met Dr. R.A.A. Bots, Dr. R.M. Castelein en Dr. Mr. J.G.M. Keet.

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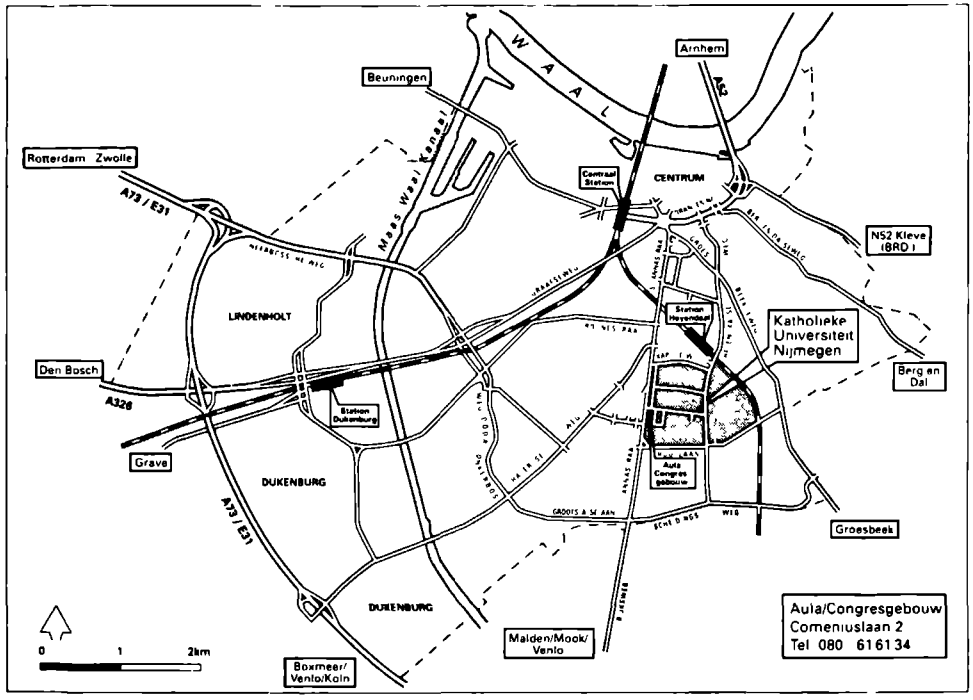
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STELLINGEN

behorende bij het proefschrift
Wear and Alignment in Total Knee Replacement
an in vivo and laboratory study

Nicolaas Josephus Antonius Tulp

1 Polyethyleen slijtage vormt de grootste bedreiging voor de levensduur van alle knieprothesen met een klein contactvlak, deze slijtage wordt nog versneld door een niet-correcte plaatsing

2 Een tibio-femorale hoekmeting op een rontgenfoto geeft onvoldoende informatie over de plaatsing van een totale knieprothese

3 Bij de pre-operatieve planning van een totale knieprothese, zijn lange staande rontgenopnamen van het hele been noodzakelijk en ook post-operatief zijn ze onmisbaar voor de juiste nabehandeling

4 Het intramedullaire femorale richtinstrument wordt foutief gebruikt ten gevolge van beperkte pre-operatieve planning

5 Het is onlogisch het slechtste onderdeel van de totale knieprothese, de patella prothese, als zelfstandige patellofemorale prothese te gebruiken

6 'Cement disease', wordt waarschijnlijk veroorzaakt door polyethyleen slijtage partikels en zou beter 'polyethyleen disease' kunnen heten

7 Vanwege verhoogde kans op polyethyleen slijtage, is het onjuist om bij jongere patienten, met alleen arthrose in het mediale of laterale compartiment, een unicondylaire knieprothese te plaatsen Een corrigerende osteotomie verdient in deze gevallen de voorkeur

8 Veel Nederlandse huisartsen en patienten hebben een negatief beeld van de knieprothese Ze beseffen echter niet dat de hieruit voortvloeiende afwachtende houding het uiteindelijke klinische resultaat van de prothese negatief beinvloedt

9 Door het ontbreken van een kwaliteits contrôlesysteem op implantaten in Nederland, zijn wij hier overgeleverd aan de kwaliteitsnorm van de belanghebbende producent

10 De kwaliteit van specialistische dienstverlening in de gezondheidszorg wordt in hoge mate bepaald door het mensbeeld van de specialist

11 Traumatologie is een multidisciplinair vakgebied en moet ook als zodanig beoefend worden

12 De orthopaedisch chirurg moet nooit blindelings op zijn timmermansoog vertrouwen Voor zijn timmerwerk thuis geldt dat juist daar de grootste ongelukken gebeuren

13 Zeker de mensen die in de gezondheidszorg werken moeten bij het kennismaken met patienten met een duidelijk letsel van de rechterarm of-hand een padvindershand geven

14 Wacht u die geneesmeester te verzetten die de eigenschap van uw natuur bekend is (uit Geneesinsighten van Nicolaes Tulp, 1716)